User Manual

DSR3100000 rev. M

CE 0482

Please read this document carefully before using the IceSense3™ cryoablation system. Do not attempt to perform any procedure before carefully reading all instructions. Always follow product labeling and manufacturer's recommendations. If in doubt as to how to proceed in any situation, contact your IceCure Medical representative.

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Contents

Figures

1 OVERVIEW

1.1 Introduction

IceSense3™ cryoablation system is a comprehensive system for cryotherapy of human tissue based on IceCure Medical's technology. All established cryotherapy techniques utilize a low temperature cryogen under pressure. The IceSense3™ cryoablation system utilizes liquid nitrogen that causes the cryoprobe to reach very low temperatures thereby freezing tissue with which it comes in contact.

1.2 Intended use

IceSense3™ cryoablation system is intended for cryogenic destruction of tissue during surgical procedures by the application of extreme cold temperatures. The IceSense3™ cryoablation system is indicated for use as a cryosurgical tool in the fields of general surgery (including breast tissue), dermatology, thoracic surgery (including lung tissue), gynecology, oncology, proctology, and urology (including kidney tissue). The IceSense3™cryoablation system may be used with an ultrasound device to provide real-time visualization of the cryosurgical procedure.

The system is suitable for use in a number of cryotherapy applications. However, it is ONLY indicated for use in patients whom the practitioner has deemed eligible for cryotherapy.

1.3 Indications for use

IceSense3™cryoablation system is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, thoracic surgery, gynecology, oncology, proctology, and urology as detailed below. The IceSense3™cryoablation system may be used with an ultrasound device to provide real-time visualization of the cryosurgical procedure.

Urology

- The system may be used to ablate prostatic tissue.
- The system may be used to ablate kidney tissue including renal cell carcinoma.
- The system may be used for the ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia.

Oncology

- The system may be used for ablation of cancerous or malignant tissue.
- The system may be used for ablation of benign tumors.
- The system may be used for palliative intervention.

Dermatology

- The system may be used for the ablation or freezing of skin cancers and other cutaneous disorders.

Gynecology

- The system may be used for the ablation of malignant neoplasia or benign dysplasia of the female genitalia.

General Surgery

- The system may be used for the ablation of leukoplakia of mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions.
- The system may be used for the destruction of warts or lesions.
- The system may be used for the palliation of tumors of the oral cavity, rectum, and skin.
- The system may be used for ablation of breast fibroadenomas.

Thoracic Surgery

- The system may be used for the ablation of arrhythmic cardiac tissue.
- The system may be used for the ablation of cancerous lesions, including lung tissue.

Proctology

- The system may be used for the ablation of benign or malignant growths of the anus and rectum
- The system may be used for the ablation of hemorrhoids.

The IceSense3™cryoablation system is indicated for patients whom the surgeon has designated as eligible for cryotherapy.

1.4 **Qualified users**

You are a qualified IceSense3™ cryoablation system user only if you meet all of the following criteria:

- You are a board certified medical practitioner licensed in your country.
- You have taken a certified IceSense3™ cryoablation system training course.
- You have read and understood all relevant material accompanying the IceSense3™ cryoablation system.

Warning
If you do not meet the above criteria, you should not use the IceSense3™ cryoablation system.

Practitioners electing to be IceSense3™ cryoablation system users must attend a training course prior to using the system. The course is taught by IceCure Medical certified personnel.

Warning
Do not use this system if you have not been adequately trained in its use.

1.5 Clinical decisions

The practitioner is solely responsible for all clinical use of the IceSense3™ cryoablation system and for any results obtained with the device.

Cryotherapy is beneficial in a variety of applications. However, sole responsibility for determining when and how to use the system with a given patient and for a particular medical condition lies with the practitioner.

Use of IceSense3™ cryoablation system in special populations, such as pregnant women, has not been established.

For further details, refer to Section 1.3 – Indications for use.

1.6 Qualified technician

Only a technician trained by IceCure Medical is qualified to service the IceSense3™ cryoablation system.

Servicing includes periodic maintenance and repair of the system.

Warning
Do not modify this equipment without authorization of the manufacturer

1.7 Advanced Operator

You are a qualified IceSense3™ cryoablation system advanced operator only if you meet all of the following criteria:

- You have taken a certified IceSense3™ cryoablation system technical training course.
- You have read and understood all relevant material accompanying the IceSense3™ cryoablation system.

Warning
If you do not meet the above criteria, you should not use the IceSense3™ cryoablation system for presentation or other marketing use.

2 SAFETY NOTES

While this manual is designed to provide instructions in the use of the IceSense3™ cryoablation system, it is not intended to take the place of the user training course which must be completed before using the system.

This chapter defines the different types of safety notices that appear in the manual.

2.1 Warnings and cautions

Safety notices appear throughout the manual and take one of the following forms:

Warning - this notice is called a Warning: it deals with danger to people.

Warning
It is dangerous for people to do this.

Caution - this notice is called a Caution: it deals with danger to equipment and data.

Caution
It is dangerous for equipment and data to do this.

2.2 Basic safety principles

All the safety issues explained in this manual are grouped within the following areas of responsibility:

2.2.1 Ownership

Warning
U.S. federal law restricts this device to sale by or on order of a physician.

2.2.2 Qualification

Warning
Any procedures using this system must be performed by licensed practitioners or board-certified doctors who are trained and experienced in the use of this system.

Warning

Do not attempt to perform any troubleshooting or corrective action beyond those specified in the following guide. Any malfunction not listed in the guide, or one that persists after the recommended action has been taken, must be referred to IceCure Medical.

Warning

Never allow untrained personnel to operate the IceSense3™ cryoablation system.

Warning

Never enter the Technician mode screen. Only an IceCure technician or authorized representative is allowed to use the technician mode for maintenance or repair of the system.

Warning

Never open the console. Only an IceCure Medical technician or authorized representative is allowed to open the console for maintenance or to repair the system.

2.2.3 **Training**

Warning

Do not use this system if you have not been adequately trained in its use.

2.2.4 **Clarity**

Warning

Do not use this system until you have read the User Manual in its entirety and fully understand its contents.

While every effort has been made to make this User Manual comprehensive, certain sections may be unclear or difficult to understand depending on the user's background and experience. Do not use this system if there is any instruction, direction, precaution or note which you do not understand or which is unclear. Never hesitate to contact an authorized IceCure Medical representative for further information and clarification before using the system.

2.2.5 **Clinical assessment**

Warning

Practitioners should be aware of the possibility of mammographic findings at the site of a cryoablated fibroadenoma. Practitioners should enquire if a patient has a history of cryoablation.

Warning

Exercise caution when treating patients who have had previous difficulty with surgical procedures or local anesthesia.

Warning

Safety and effectiveness of the IceSense3™ cryoablation system in pregnant women has not been established. Physicians should exercise caution when using IceSense3™ cryoablation system in pregnant women.

Warning

The handle and hose portions of the IceSense3™ cryoablation system may become cold during the cryoablation procedure. Operators should consider insulating these parts in order to prevent discomfort to the patient.

Warning

The supplier and manufacturer of the IceSense3™ cryoablation system do not claim that it will be useful for assisting with the treatment of any particular condition or set of circumstances. Full responsibility for assessing the potential benefit of the system for a given medical condition lies with the practitioner.
While experience has shown that the system is useful for certain applications in cryosurgery, no representation or warranty is made that the system is useful for any specific person or condition.

Warning

For patients with breast implants, you must document that adequate distance exists between the lesion and the implant to ensure that the ablated lesion will not contact or jeopardize the implant

Warning
Do not rely solely on the temperature sensor measurement. Always monitor the procedure using Ultrasound or other appropriate imaging system.

Warning
Temperature sensor insertion and navigation within tissue MUST be done under guidance of an appropriate imaging device.

2.2.6 Installation and setup

Warning
The IceSense3™ cryoablation system should be operated in an adequately ventilated room. Failure to do so may result in risk of suffocation due to increased levels of nitrogen in the room..

Caution
After positioning the main chassis, lock the front roller brakes. Failure to do so may result in damage to the system or to other equipment in the clinic room.

Caution
The IceSense3™ cryoablation system must be unpacked, installed, and tested by an IceCure Medical authorized technician only

Caution
There are no user-serviceable parts in the system. Refer all service issues to IceCure Medical's Customer Service Department.

Caution
Make sure the time is set according to local time zone before executing a cryotherapy procedure.

2.2.7 **Proper use**

Caution
Do not use the workstation or the liquid nitrogen Dewar for any purpose other than operating the IceSense3™ cryoablation system.

Caution
The liquid nitrogen Dewar supplied with the IceSense3™ cryoablation system is a dedicated system part and should not be used for any other purpose. Make sure to use only the adequate Dewar for your system.

Caution
Dewars should always be stored with their lids in place.

Caution
Only Dewars and lids supplied by IceCure Medical may be used with the IceSense3™ cryoablation system. Make sure to use only the adequate Dewar for your system.

Warning
Always turn off the IceSense3™ cryoablation system and lock the wheels when not in use.
Before you start a procedure lock two of the four wheels.

Caution
The IceSense3™ cryoablation system should be moved with care in order to avoid damage to the system or other clinical equipment.

Warning
If one or more of the wheels is damaged, do not use the system.

Warning
Cryoprobes are fragile and can be damage if mishandled. Do not use a cryoprobe that has been bent, dropped, hit against a hard surface or compromised in any manner, as internal damage to the cryoprobe may have occurred.

Caution
Do not move the system when the Dewar contains liquid nitrogen.

Warning
Removing the Dewar, or placing it back within the system after refilling it must ONLY be done according to system instruction and with the carriage in the bottom position. If the carriage is not in the bottom position, liquid nitrogen may spill out.

Caution
Follow the detailed instructions on open the Dewar storage- when you want to replace a Dewar.

Caution
The system will not allow additional treatment when zero procedures left to maintenance. Make sure to call IceCure Medical service representatives in time.

2.3 Operating warnings

Warning
Ensure that the cryoprobe is securely connected.

Warning
Ensure that the temperature sensor is securely connected.

Warning
Insertion of the cryoprobe into the target tissue is performed under the guidance of an appropriate imaging device and by an authorized practitioner trained by IceCure medical.

Warning
The probe must be IN THE TARGET TISSUE BEFORE starting the freeze treatment.

Warning
The practitioner must hold the cryohandle for the duration of the cryoablation procedure.

Warning
If the procedure is not yet underway after a cryoprobe is screwed onto the cryohandle, hang the cryohandle in its holder to prevent a stabbing injury from the cryoprobe.
Be sure to maintain sterility of the cryohandle and cryoprobe.

Warning
Before removing the cryoprobe from the tissue, make sure that the freeze effect has been deactivated so that the probe can easily be removed from the tissue.
Do not force removal of the cryoprobe from the tissue as it might increase the risk of hematoma.
Continue the Warm step or wait for passive thaw until the cryoprobe can be withdrawn easily

Warning

Before removing the temperature sensor from the tissue, make sure the freeze effect has been deactivated and the sensor can be easily withdrawn. Never use excessive force to extract the temperature sensor.

Warning

DO NOT push the warm button when the cryoprobe is not within the target tissue, as skin burns could occur and not before the freezing protocol is completed, unless you want to shorten the procedure due to clinical judgment.

Warning

Never detach the cryoprobe from the cryohandle if you are not clearly required to unscrew or disengage it.

Caution

Verify cryoprobe S/N registration by double checking the serial number on the package and on the cryoprobe itself. Entering an incorrect cryoprobe S/N registration will result in probe nullification.

Warning

Do not allow any liquid or humidity to enter the cryohandle. Always keep the cover on the cryohandle.

Warning

In case of the active Warm process isn't available, Wait for passive Thaw.

Warning

In case of frost on shaft, if possible start active Warm. If not, wait for passive Thaw. In both cases use skin protection techniques.

2.4 Liquid nitrogen

Nitrogen gas is a potential asphyxiant. In the event of a large liquid nitrogen spill, personnel should adhere to a predetermined evacuation plan. Seek medical help immediately if breathing problems occur.

Warning
If a liquid nitrogen leak is detected at any time, PUSH the Warm button immediately.

2.4.1 Danger - explosion and fire hazard

Warning
The IceSense3™ cryoablation system includes electronic devices that may emit sparks and should therefore not be operated in the presence of ANY flammable material.

IceSense3™ cryoablation system should be kept away from flammable fumes, e.g., flammable anesthetics or volatile substances. An easily accessible fire extinguisher in the vicinity of the unit is recommended.

2.4.2 Opening the Dewar compartment

Caution
Never open the Dewar compartment while running a cryoablation procedure. Do not use the system while the Dewar compartment is open.

Warning
Do not transfer a Dewar with Liquid nitrogen unless it is covered with its designated lid.

Caution
Follow the specific instructions on how to fill and transfer a Dewar as described in section 5.2.7.1 – Dewar.

2.4.3 **Voltage and power ratings**

Caution

Verify that the IceSense3™ cryoablation system complies with the local voltage line.

2.4.4 **Liquid nitrogen Safety**

Warning

Liquid nitrogen may cause serious injury or burn if handled improperly. Local laws and safety rules regarding the maintenance and handling of liquid nitrogen Dewars should always be observed. Maintenance of liquid nitrogen Dewars should be performed by authorized personnel only.

Warning

Do not use a liquid nitrogen Dewar if it is damaged.

You can tell that a Dewar is damaged if after filling it, frost appears on the outer wall of the container. Return the Dewar to IceCure technician or an authorized distributor for inspection

Standard guidelines for safe handling and storage of liquid nitrogen are available from the supplier and must be carefully observed.

The following is a list of general safety points that should be followed at all times:

Handle liquid nitrogen with care. Contact with skin may cause serious frostbite. Do not allow objects cooled by liquid nitrogen to touch your bare skin. Objects cooled by liquid nitrogen may stick to the skin and tear flesh when attempting removal.

Protective clothing can reduce the hazards of handling liquid nitrogen. Insulated or heavy leather gloves should always be worn when handling any object that has been in contact with liquid nitrogen. Loose fitting gloves are recommended so that they may be discarded quickly in the event that any liquid nitrogen splashes into them. If you are working with open containers of liquid nitrogen, boots should be worn and trousers should not be tucked into boots, but worn outside.

Personal protective equipment is essential and can save you from liquid nitrogen's risks. Full face shield and safety glasses are recommended for eyes/face protection.

Fill the container slowly to avoid the expansion stress that occurs as a result of the rapid cooling. Too much pressure can damage the container.

Do not seal the containers tightly. The use of a tight-fitting stopper or plug that prevents the adequate venting of gas allows a build-up of pressure that could severely damage or even burst the container. Even an accumulation of ice or frost on the lid can interfere with proper venting. To assure safe operation, only use the original sponge lid supplied with the dewar.

Liquid nitrogen containers should always be stored in an upright position. Tipping the container or letting it lie on its side can result in spillage and may damage the container. Dropping the container or subjecting it to severe vibration may damage the vacuum insulation system.

Transfer liquid nitrogen with care. Spilling and splashing are the primary hazards of transferring liquid nitrogen from one container to another. NEVER overfill the containers. Filling above the specified level is likely to produce spillage when the lid is replaced. Transportation of liquid nitrogen must always be done in the original container and in accordance with local laws and safety rules.

Do not attempt to dispose of residual or unused quantities of liquid nitrogen. For safe disposal contact your supplier. For emergency disposal, discharge slowly to the atmosphere in a well-ventilated room or outdoors.

If spilled liquid nitrogen causes a cloud to form, the room must be evacuated and ventilated immediately. Anyone experiencing headache, dizziness, difficulty breathing, or other symptoms of hypoxia should receive immediate medical attention.

Do not use a liquid nitrogen Dewar if it is damaged. You can tell that a Dewar is damaged if after filling it, frost appears on the outer wall of the container. Return the Dewar to an IceCure technician or an authorized distributor for inspection.

Warning

Before beginning a procedure on a new patient, the Dewar MUST be completely filled and placed in the system as described in section 5.2.7.1 of this manual.

2.4.5 Burn hazards

The Cryoprobe tip can reach very low temperatures.

Warning

Portions of the cryoprobe other than the freeze zone, including the plastic cover that is located near the cryoprobe handle, may become cold and cause tissue damage. If unwanted freezing occurs, stop the pre-test process by pressing "Cancel".

Warning

Portions of the cryoprobe other than the freeze zone, including the plastic cover that is located near the cryoprobe handle, may become cold and cause tissue damage. If unwanted freezing occurs, immediately stop the freezing process.
To prevent injury, cryoprobes must be closely observed during use for signs of unwanted freezing.

2.4.6 **Grounding**

Warning
To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

2.4.7 **Sterility**

Warning
The cryoprobes and the temperature sensors are single use and are supplied in single use packaging. Never reuse a single-use cryoprobe, temperature sensor, or sterile sleeve. Reprocessing single use device (like the cryoprobe, temperature sensor) affects the mechanical, performance, and microbiological properties of the product.

Warning
After finishing the surgical procedure on a patient, remove and discard the single-use cryoprobe, temperature sensor, and sterile sleeve.

Warning
For each new patient, ensure that the previously used single-use cryoprobe, temperature sensor, and sterile sleeve have been removed and discarded. Any used cryoprobe and temperature sensor should be related as used sharp biohazard waste.

2.4.8 **Mechanical handling of flexible hose and cryohandle**

Warning
Never use excessive force to insert or remove a cryoprobe from the cryohandle.
If moderate force is not sufficient, contact IceCure Medical for advice.

2.5 **Emergencies and errors**

2.5.1 **Emergency Stop button**

Caution

Only push the Emergency Stop button when there is NO other choice. Whenever possible, use Warm to release the probe from the tissue and use the standard shutdown procedure.

Excessive use of the Emergency Stop button may damage the system.

Warning

If a major electrical risk is detected during the cryotherapy procedure, PUSH the Emergency Stop button immediately.

2.5.2 Emergencies causing procedure halt

Warning

When a procedure halts due to an error, switch off the system. Call IceCure Medical and describe the error shown on the screen as precisely as possible.
Do NOT attempt to reuse the system before contacting IceCure Medical.

Warning

When an error message is displayed and a procedure is aborted, remove the probe ONLY after you are allowed to do so by the system. Failure to do so will increase the risk of liquid nitrogen related accident.

Warning

In case of software crash, switch OFF the mechanical ON/OFF button and unplug the electrical cable. Call IceCure Medical for technical service before restarting the IceSense3™ cryoablation system.

Warning

When the system shuts itself down due to an error, contact IceCure Medical and describe the error message shown on the screen as precisely as possible. Do not attempt to reuse the system before contacting IceCure Medical. After reporting or making note of the error message, switch OFF the mechanical ON/OFF button and unplug the electrical cable.

2.6 Adverse events

Warning

Regulatory requirements mandate that serious adverse events be reported to the relevant regulatory authorities. Users must notify IceCure Medical of all serious adverse events including serious adverse device reactions no later than 24 hours following receipt of such information.

2.7 Compliance

2.7.1 Compliance with international safety standards

The IceSense3™cryoablation system was designed and built in accordance with ASTM international standards, Designation F882-84 - Standard Performance and Safety Specification for Cryosurgical Medical Instruments (re-approved in 1996).

- EN 60601-1 Standard for safety of Medical equipment
- European MDD 93/42/EEC
- EN 60601-1-2 Standards for Electromagnetic compatibility of medical electrical equipment (See chapter 16 - Manufacturer's Declaration of the EUT)

2.8 Equipment classification

- Electric shock protection: Class I, Type BF.
- Protection against ingress of liquids: ordinary equipment.
- Not suitable for use in presence of flammable anesthetic mixture with air or nitrous oxide.

2.9 Accompanying labels

Label 1 – On/off mechanical button on the console

Label 2 – Emergency Stop button

Label 3 – Identification with the manufacturer's name and address, date of manufacture, unit model and serial number, and electrical specifications.

Label 4 – CAUTION Federal (USA) law restricts this device to sale by or on order of a licensed practitioner.

Label 5 – Read User Manual before use

Label 6 – CAUTION HIGH VOLTAGE: Before working on this unit

- Switch off power supply
- Disconnect all plugs

Label 7 – DANGER Line voltage

Label 8 – Foot pedal (Not available in some regions, e.g. China)

Label 9 – DANGER: Risk of explosion if used in the presence of flammable anesthetics. CAUTION: To reduce risk of electrical shock, do not remove cover. Refer servicing to qualified service personnel.

Label 10 – Single use probe

Label 11 – Single use temperature sensor

Label 12 – Liquid Nitrogen Dewar

Label 13 - Black Dewar

Label 14 – COLD area

Label 15- Empty LN2 Dewars

Label 16- Applied parts

Label 17- Shipping Art Work

There are additional labels inside the system that are not visible to the user. These labels are intended for the technician.

System Labels:

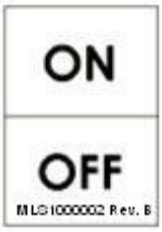


Figure 1: Label 1 - On/Off mechanical button - MLS1000002 Rev. B

Figure 2: Label 2 - Emergency Stop - MLS1000003 Rev. B

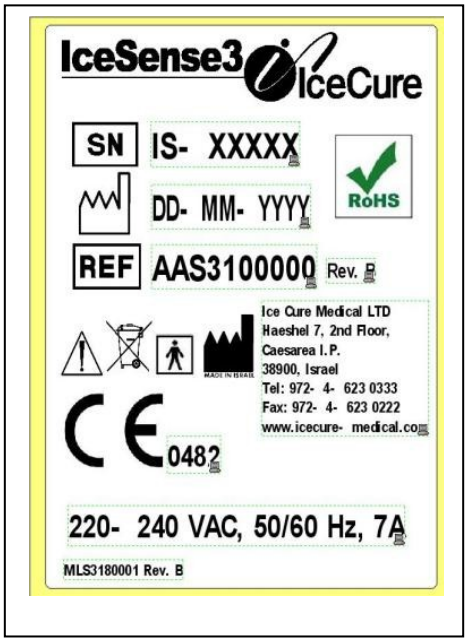


Figure 3 : Label 3 - Identification - MLS3180001 Rev. B

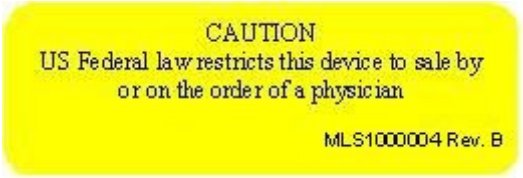


Figure 4 : Label 4 - Federal laws restriction - MLS1000004 Rev. B

Figure 5 : Label 5 - Follow instructions for use - MLS1000005 Rev. C

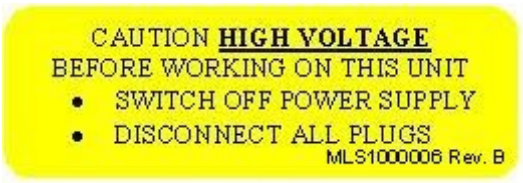


Figure 6: Label 6 - High voltage caution - MLS1000006 Rev. B

Figure 7: Label 7 - Line voltage danger - MLS1000007 Rev. B

Figure 8: Label 8 - Foot pedal - MLS1000008 Rev. B

Figure 9: Label 9 - Risk of Explosion - MLS1000009 Rev. B

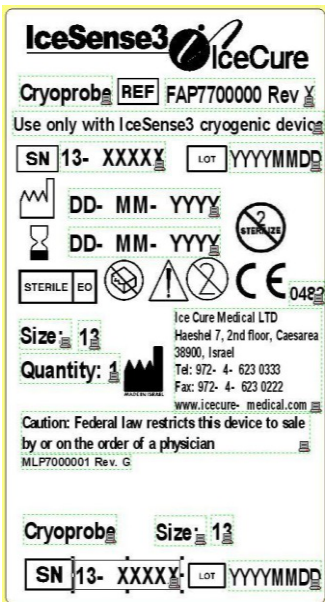


Figure 10:: Label10 - Single use probe - MLP7000001 Rev. F

Figure 11: Label 11 - Single use temperature sensor - MLT8000001 Rev. G

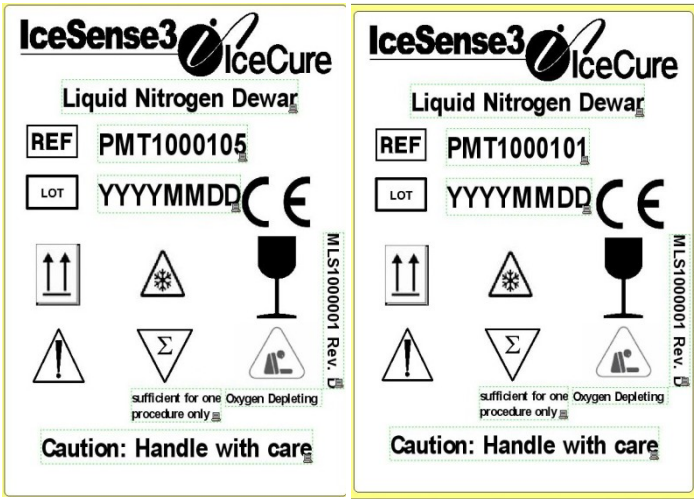


Figure 12: Label 12 - Liquid nitrogen Dewar - MLS1000001 Rev. D

Figure 13: Label 13 - Black Dewar - MLS1000015 Rev. A

Figure 14: Label 14 – Cold area - MLS1000010 Rev. B

Figure 15: Label 15- Empty LN2 dewars - MLS1000012 Rev. A

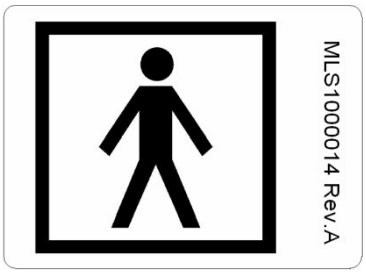


Figure 16: Label 16- Applied parts - MLS1000014 Rev. A

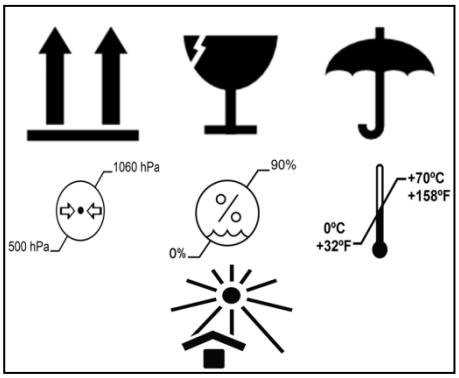


Figure 17: Label 17- Shipping Art Work

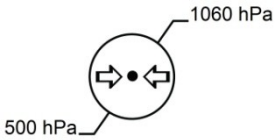
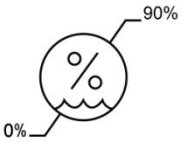
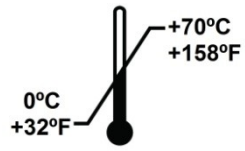
2.9.1 **Important Symbols and Labels**

A number of internationally recognized symbols relating to safety requirements and standards are found on the IceSense3™ cryoablation system. These symbols are listed in the table below.

Table 1.1 International Symbols on IceSense3™ cryoablation system

Symbol	Meaning
	Caution-Warning
	Applied parts
CLASS 1	Class 1
	Serial number
	Manufacturer
	Date of manufacture
	Do not reuse
	Use- by Date
	Catalogue number
	Do not resterilize
	Sterilized using ethylene oxide

Symbol	Meaning
	Batch code
	Contains sufficient for <n> test
	The WEEE symbol indicates that this system contains electrical and electronic components that must be collected and disposed of separately. Never dispose of electrical and electronic components in general municipal waste receptacles. Electrical and electronic equipment contain hazardous substances which, when disposed of incorrectly, may leak into the ground. This can contribute to soil and water pollution which is hazardous to human health and endangers wildlife. Therefore, such equipment must not be disposed of in landfill sites or incinerators. Contact your local authority or place of purchase regarding responsible disposal/recycling.
	Fragile, handle with care
	Do not use if package is damaged
	Cold area
	Consult instructions for use
	Oxygen depleting

Symbol	Meaning
	This side up
	Authorized representative in the European community
	CE mark- mandatory conformity mark for products placed on the market in the European Economic Area
	Transportation and storage atmospheric pressure limits
	Transportation and storage humidity limits
	Storage temperature limits
	Keep away from sunlight

3 SYSTEM DESCRIPTION

3.1 Introduction

This chapter contains the following:

- Concept of operation – IceSense3™ cryoablation system intention for use
- Major components – description of the main system parts
- Operational details – system processes that occur as a result of user actions

3.2 Concept of operation

The IceSense3™ cryoablation system is intended for cryogenic destruction of tissue during surgical procedures. It is indicated for use as a cryosurgical tool in a number of medical fields.

The system is designed to destroy tissue by the application of extreme cold temperatures.

IceSense3™ cryoablation system is indicated for patients whom the practitioner has designated as eligible for cryotherapy.

3.3 Major components

The following figure illustrates external features of the IceSense3™ cryoablation system:

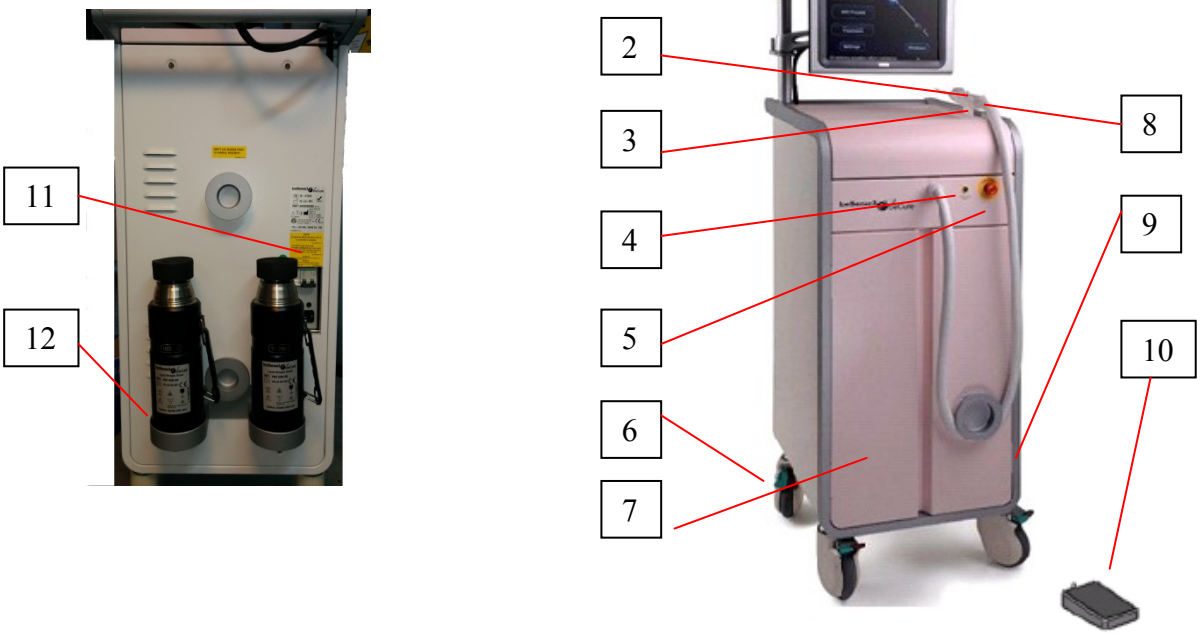


Figure 18: Front and back view of the IceSense3™ cryoablation system with numbered components

1. Touch screen
2. Cryoprobe holder
3. Cryohandle
4. Temperature sensor connector
5. Emergency button
6. Rollers
7. Dewar positioning door
8. Handle plug holder
9. Foot pedal connector
10. Foot pedal (Not available in some regions, e.g. China)
11. On-off switch
12. Dewar storage cases

The IceSense3™ cryoablation system includes:

- Main chassis
- Adjustable touch screen
- External accessories: foot pedal (Not available in some regions, e.g. China), temperature sensor connected to the main chassis, and single use cryoprobe connected to a cryohandle

3.3.1 **Main chassis**

The IceSense3™ cryoablation system is housed within a chassis mounted on four rollers for ease of movement. Each roller is equipped with directional and rotational brakes for system immobilization. Located on the top of the chassis are a touch screen control panel and a cryohandle holder. On the right upper part of the chassis is the Emergency Stop button - a round red button that shuts down the system immediately in an emergency situation. On the back of the chassis are two hooks used for hanging the electric cable, and a grip handle for ease of system transportation.

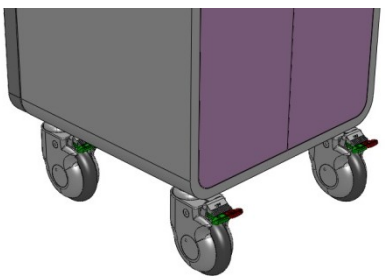


Figure 19: The IceSense3™ transportation rollers & brakes

3.3.2 Emergency Stop button

The Emergency Stop button is a red knob located on the right upper side of the chassis. It is designed for emergency shutdown of the unit. Pressing this button immediately turns off the electrical power supply to the system. To release the Emergency Stop button, turn it in the direction of the arrows.

Figure 20: The Emergency Stop button

Caution
Only push the Emergency Stop button when there is NO other choice. Whenever possible, use Warm to release the probe from the tissue and use the standard shutdown procedure. Excessive use of the Emergency Stop button may damage the system.

Warning
If a major electrical risk is detected during the cryotherapy procedure, PUSH the Emergency Stop button immediately.

3.3.3 Flexible hose

The flexible hose joins the cryohandle to the siphon inside the chassis. This permits nitrogen to flow from the main chassis to the probe.

Caution
Do not pull the system by the cryohandle or flexible hose.
The flexible hose shouldn’t be bent or flexed during procedure.

3.3.4 Touch screen and User Manual activation

The touch screen is located on the top of the main chassis and allows for operating and monitoring of the system. It is designed for users and technicians.

Do not connect any signal input/output port to the touch panel PC except medical certified equipment provided by IceCure Medical.
A sample touch screen display is represented by the figure below. For further information about computer interface and operating the system, see Chapter 6.

Figure 21: The touch screen display before a cryoablation procedure

From the screen, the User Manual is not accessible during the procedure: if you try to open it during the procedure, it will open only after the procedure's end.

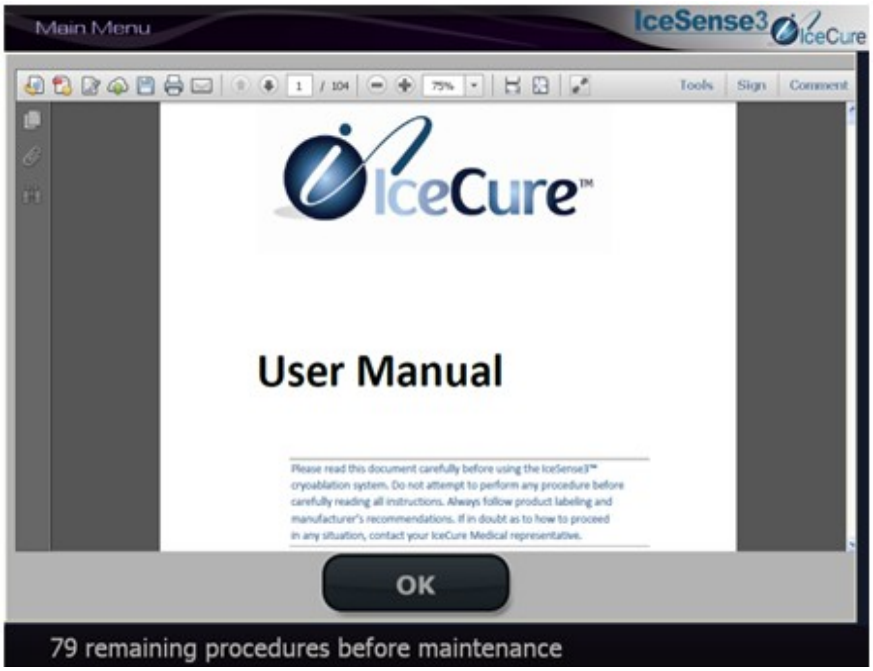


Figure 22: The User Manual screen

You can choose the part you want to read from the **Table of Contents**: click on it, and you will access it directly.

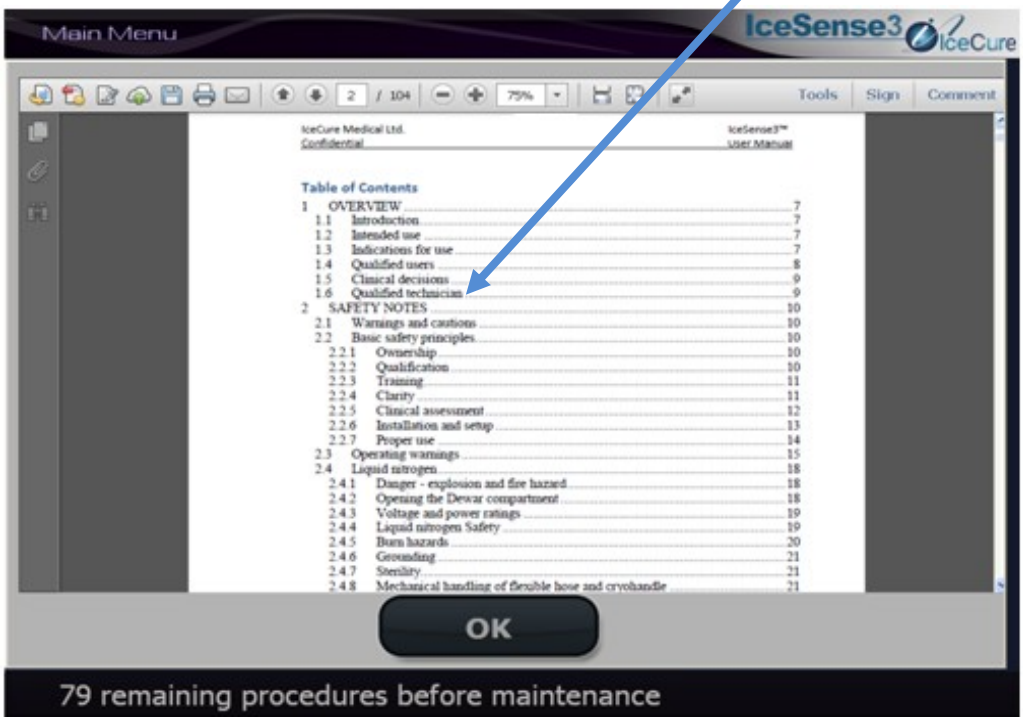


Figure 23: The User Manual Table of contents

You can select a **page number**, **zoom in** or **zoom out**, **scroll** along the document.

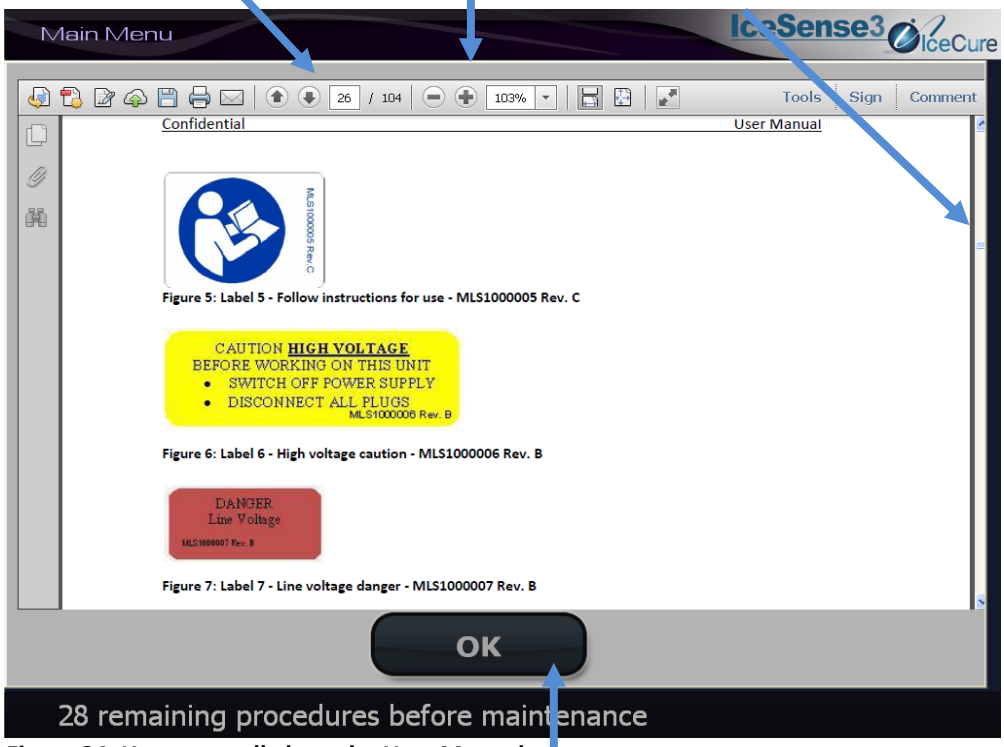


Figure 24: How to scroll along the User Manual

By pressing OK, you will exit the User Manual.

If you prefer, you can also download the User Manual from our website:

http://www.icecure-medical.com

For confidentiality and security reasons, the access is protected. Please use the Personal Password you received from your IceCure Medical representative.

3.3.5 **Cryohandle and cryoprobe**

The cryohandle is situated at the end of the flexible hose that projects through the upper area of the front panel of the IceSense3™ cryoablation system unit. The cryoprobe is connected to the cryohandle. The cryohandle allows for maneuvering of the cryoprobe within the target tissue.

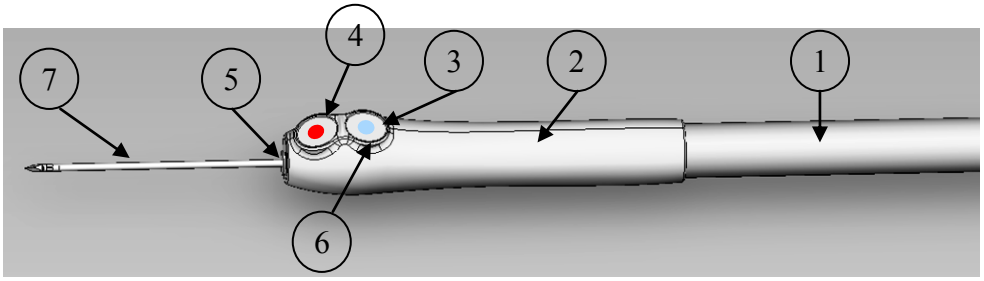


Figure 25: The flexible hose, cryohandle and connected cryoprobe

1. Flexible hose
2. Cryohandle
3. Action button (allows the user to select actions that appears on the screen)
4. Warm button (activates/deactivates the warm function)
5. Cryoprobe insertion point
6. LED indicator displaying **BLUE** to indicate the freeze mode is ON
7. Cryoprobe

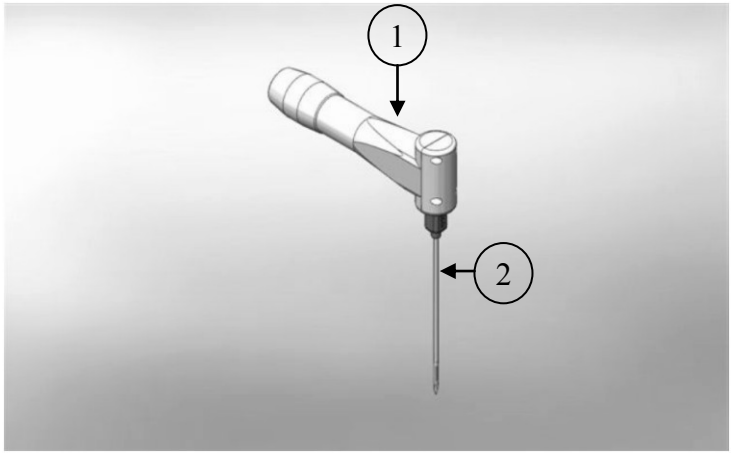


Figure 26: The 90 degrees cryohandle and connected cryoprobe (Not available in some regions, e.g. USA)

1. Cryohandle
2. Cryoprobe

Warning
Never reuse a single-use cryoprobe, temperature sensor or sterile sleeve.

Warning
At the conclusion of each patient session, remove and discard the single-use cryoprobe, temperature sensor and sterile sleeve.

3.3.6 Handle plug holder

The handle plug holder is located on the top of the main chassis and allows a place for keeping the plug while performing the procedure.
Humidity is a crucial issue to address in cryosurgery systems.

- After every procedure, close the handle plug on the Cryohandle.
- Perform pretest at close proximity to the procedure treatment.

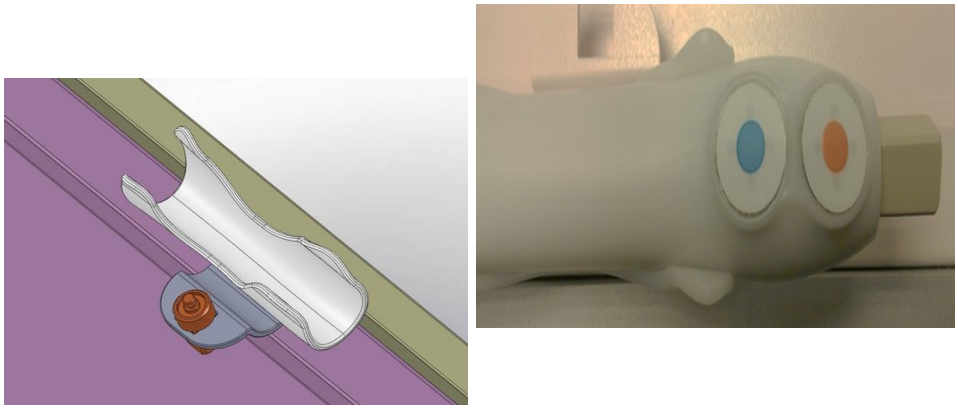


Figure 27: Handle plug holder and handle plug.

3.3.7 Foot pedal (Not available in some regions, e.g. China)

The pedal is an alternative to the Action button on the cryohandle; pushing the pneumatic foot pedal is identical to pushing the Action button.

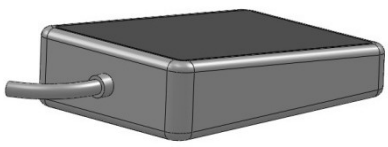


Figure 28: The foot pedal

3.3.8 **Temperature sensor (TS)**

The temperature sensor is a single use accessory that provides real time temperature measurements when inserted in tissue. Use of temperature sensors is optional; the decision to use a temperature sensor must be made before the system pretest is initiated.

Prior to starting a procedure, the temperature sensor is connected to the system and inserted into the desired location within the tissue. Insert the sensor at location that gives useful information about the progress of the freezing procedure. For example, the temperature sensor can be placed near the boundary of a tumor to ensure that the entire tumor has been frozen. Alternatively, the temperature sensor may be placed near an organ that should not be frozen during the procedure to ensure that the ice front has not advanced to this location.

The temperature sensor is not indicated for measuring the body temperature, but only for getting temperature indication of some tissue during cryoablation.

Warning

Do not rely solely on the temperature sensor measurement. Always monitor the procedure using Ultrasound or other appropriate imaging system.

The temperature sensor and its components are depicted in the following figure.

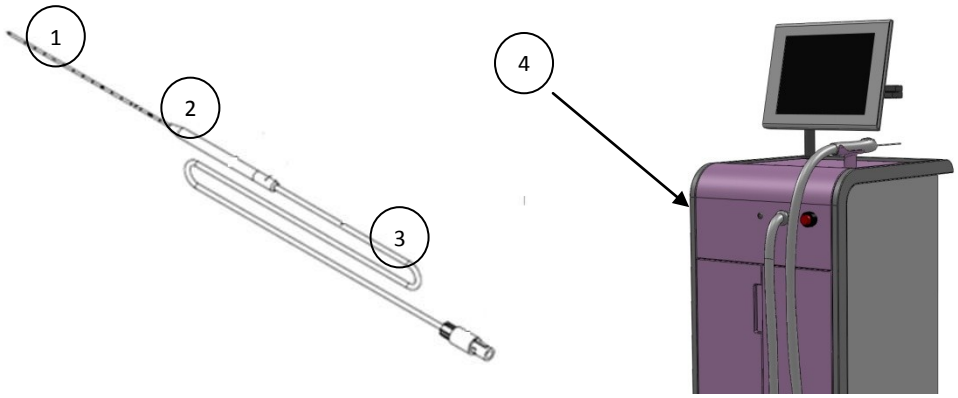


Figure 29: The temperature sensor and its components

1. Temperature sensor needle
2. Temperature sensor handle
3. Temperature sensor cable connector
4. Temperature sensor connection site

If you decide to use a temperature sensor, connect it per the following instructions while maintaining sterility:

1. Remove the temperature sensor from the sterile package.

2. Connect the cable connector to the panel connector on the upper right corner of the main chassis while keeping the connector key facing the groove.
3. The measured temperature from the sensor tip will appear on the right lower corner of the screen.
4. Under imaging guidance, insert the tip of the temperature sensor into the tissue you want to measure.
5. At the end of the procedure, gently remove the temperature sensor from the tissue and discard it.

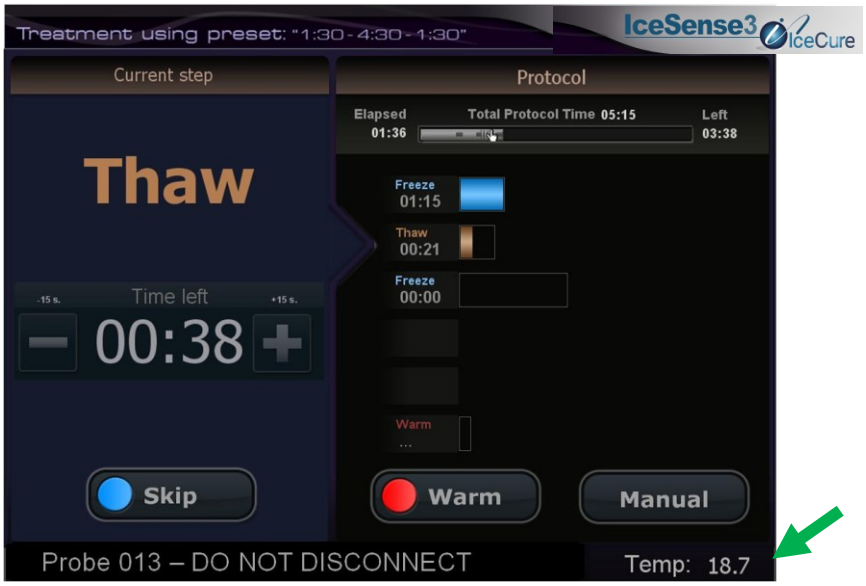


Figure 30: Temperature display of sensor in the procedure screen (green arrow)

Warning

Temperature sensor insertion and navigation within tissue MUST be done under guidance of an appropriate imaging device.

3.3.9 Dewar storage cases

The Dewar storage cases are located at the back of the chassis. They provide storage for the Dewars. When placing the Dewars inside the storage cases make sure they are well in stored (see fig. below)

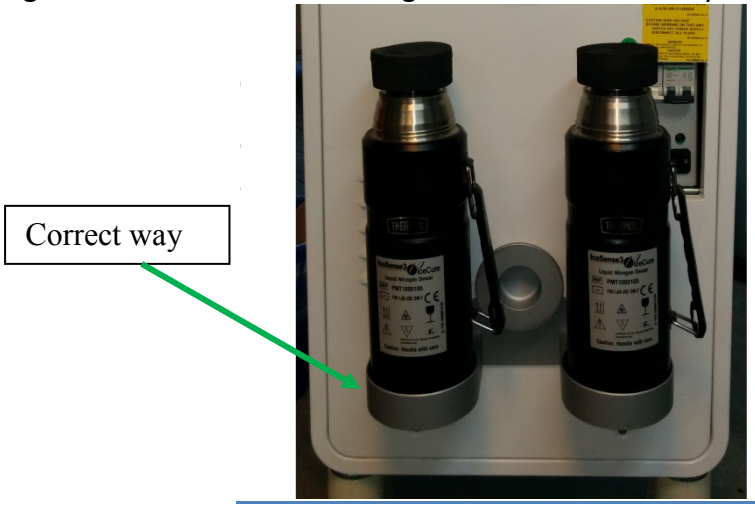


Figure 31: Dewar storage cases – the correct way to put the Dewars inside the storage cases.

Safe transportation

When moving the system from one location to another the Dewars should be empty.

3.4 Operational details

This section describes the operational actions of the IceSense3™cryoablation system that support the functional operations described in Chapter 5.

- Order liquid nitrogen in advance based on projected case load.
- Industrial grade liquid nitrogen should be delivered to the user's site in a standard cryogenic dewar.
- Follow standard guidelines for the safe handling and storage of the dewar.

Warning

Liquid nitrogen may cause serious injury or burn if handled improperly. Local laws and safety rules regarding the maintenance and handling of liquid nitrogen dewars should always be observed. Maintenance of liquid nitrogen should be performed by authorized personnel

- Care must be taken when filling the system dewar.
- Standard guidelines for safe handling and storage of liquid nitrogen should be followed. These guidelines are available from the supplier.

3.4.1 Starting the system

Before turning on the system, confirm the following conditions:

- Previously used cryoprobe, temperature sensors and sleeves have been removed and the system has been cleaned of any residue and dried off.
- The system is connected to the electrical outlet.

To switch the system ON, turn on the mechanical button at the back of the system, the touch screen will turn on and the following screen will appear:

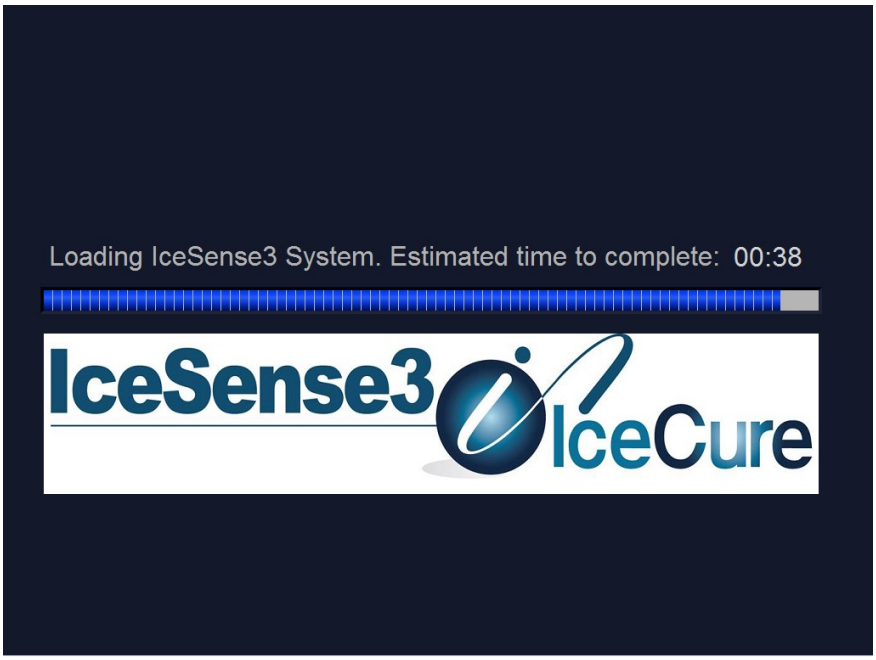


Figure 32: The system is loading screen

Wait for the Main Menu screen to load.

Figure 33: The Main Menu screen

3.4.2 System pre-tests

As the system uploads, several internal built-in tests are performed automatically in order to verify that the system is safe for use. Additional specific tests will be made upon visual inspection by the user, following instructions on the graphic interface. Each probe must be tested before use.

3.4.3 **Cryoablation procedure**

The cryoablation procedure can only be performed after the cryoprobe has been inserted in the target tissue. It can be activated by **Manual mode** (controlled by the user) or by **Automatic mode** (pre-programmed and monitored by the computer). During the entire procedure, the system continues its internal check. In case of system error, the user will be instructed as to the appropriate solution.

3.4.4 **Warm step**

Warm is a process activated automatically by the system at the end of every automatic protocol, or manually by the user at any time in the process. During this process, the cryoprobe tip is heated by warmed Nitrogen gas, enabling fast and safe removal of the probe.

4 INSTALLATION AND SETUP

4.1 Space and positioning requirements

The work area for the unit should be prepared as per the dimensions described in the system specifications (chapter 11). In order to guarantee sufficient ventilation, always maintain a clearance distance of at least 0.5 meters (20 inches) between the unit and walls or other objects that may obstruct air flow.

Adequate ventilation and air circulation are major considerations when working with liquid nitrogen.

Warning
Liquid nitrogen may cause serious injury or burn if handled improperly. Local laws and safety rules regarding the maintenance and handling of liquid nitrogen Dewars should always be observed.

4.2 Setup warnings and cautions

Warning
If there is not sufficient ventilation in the room, the IceSense3™ cryoablation system cannot be used due to risk of suffocation due to increased levels of nitrogen in the room.

Caution
The IceSense3™ cryoablation system must be unpacked, installed, and tested by an IceCure Medical authorized technician only.

Caution
After positioning the main chassis, lock the front roller brakes. Failure to do so may result in damage to the system or to other equipment in the clinic room.

Caution
Do not move the system when the Dewar contains liquid nitrogen.

4.3 Electrical requirements

The IceSense3™ cryoablation system is pre-wired for the local line voltage as specified by the user. Accordingly, the unit will require a line supply of **220-240 VAC, 50/60 Hz, 7A single phase**.
The unit is grounded through the power cable that is plugged into the wall power outlet. Good grounding is essential for safe operation. The main circuit breaker for the unit is 10 A. The circuit breaker is located in the main chassis.

4.4 Shipment components

The IceSense3™ cryoablation system is packed and shipped in separate units as follows:

- Main system
- User manual
- Two empty Dewars
- Accessories: foot pedal (Not available in some regions, e.g. China), single use probe kit, single use temperature sensors.

Sterile sleeves, sterile cover for the cryohandle holder, liquid nitrogen and disinfecting wipes – not supplied with the system.

4.5 Installation

Warning
The IceSense3™ cryoablation system must be unpacked, installed, and tested by an IceCure Medical authorized technician only and in accordance with the unpacking instructions manual.

Any damage to the container or to the unit discovered upon unpacking, installing, or testing should be immediately reported to your IceSense3™ cryoablation system distributor.

5 OPERATING THE SYSTEM

This chapter explains how to use the IceSense3™ cryoablation system and includes pre-operational, operational and post-operational steps.

Note: This User Manual describes how to operate the device with a percutaneous cryoprobe that requires imaging device for its clinical application.

The device can be used with a blunt cryoprobe for topical indications that are performed without ultrasound imaging. For topical applications the practitioner should follow standard clinical procedures that are not within the scope of this user manual.

The device can also be used for open surgical applications performed without the use of imaging device. For these applications the practitioner should follow standard clinical procedures that are not within the scope of this user manual.

TRAINING: Practitioners electing to be IceSense3™ cryoablation system users must attend a training course prior to using the system. The course is taught by IceCure Medical certified personnel.

5.1 Procedure Overview

- Patient and system preparation
- Probe selection
- System set-up and pretest
- Probe placement
- Cryoablation cycle
- End of procedure

5.2 Pre-operational stages

5.2.1 Preparing the system for procedure

1. If a probe is still connected to the cryohandle, remove and discard used probe from the handle.
2. Remove previously used single-use sterile sleeve from the cryohandle.
3. Close the cryohandle with the covering plug.
4. Arrange a sterile work environment in accordance with accepted standards.

5.2.2 Preparing the patient for procedure

1. Position patient comfortably so that the target area is easily accessible and trajectory of the probe is safe. For example: in the treatment of FA it is desirable that the probe will be placed parallel to the chest wall.

2. Measure with an imaging device the lesion in all dimensions prior to procedure to determine long axis and point of entry.
3. See Figure below for a schematic illustration of the placement of the system and the patient in the treatment room.

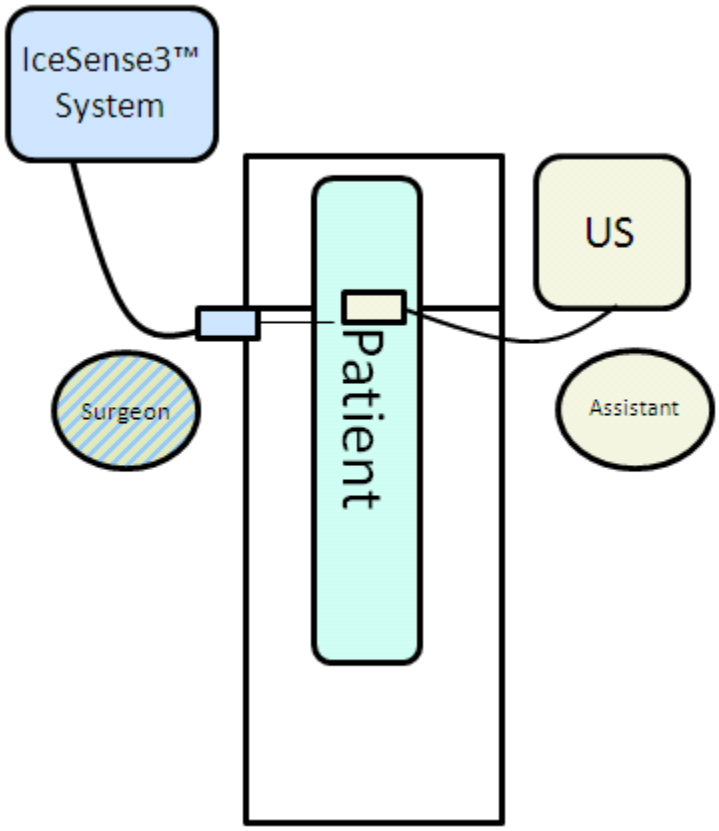


Figure 34 : Schematic illustration of placement of the system and patient.

Warning

The handle and hose portions of the IceSense3™ cryoablation system may become cold during the cryoablation procedure. Operators should consider insulating these parts in order to prevent discomfort to the patient.

Warning

For patients with breast implants, you must document that adequate distance exists between the lesion and the implant to ensure that the ablated lesion will not contact or jeopardize the implant

5.2.3 Switching on the IceSense3™ cryoablation system

Before operating the system, make sure the following conditions are in place:

- Ultrasound or other appropriate imaging system is available for monitoring the medical procedure. In case of open surgery or superficial cryotherapy, no external imaging device is required.

- The mechanical power switch is OFF.
- The cryohandle, flexible hose and cryoholder are all clean and dry.

To Switch on the IceSense3™ cryoablation system:

To switch the system ON, turn on the mechanical button at the back of the system, the touch screen will turn on and the following screen will appear:

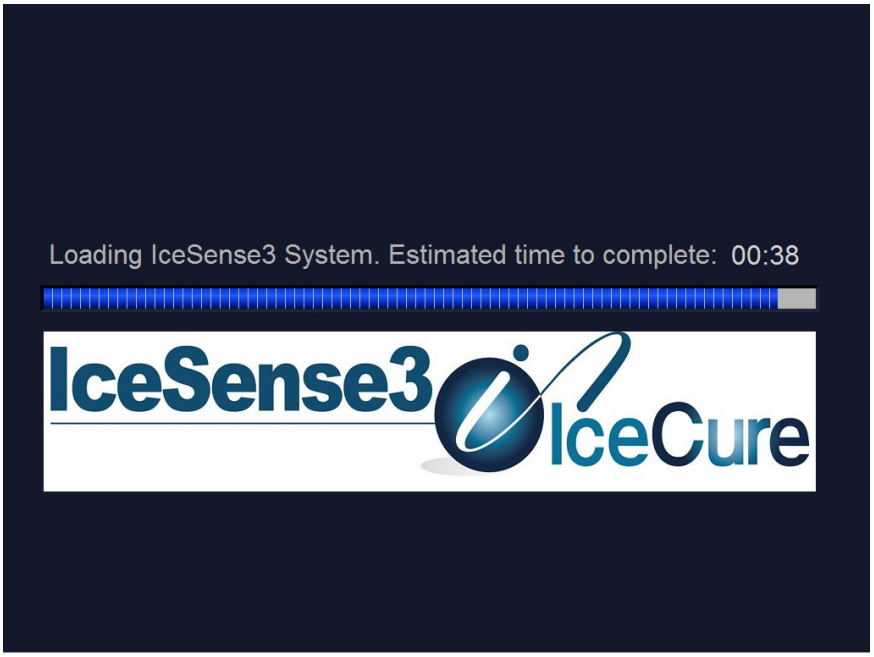


Figure 35: The system is loading screen

Wait for the Main Menu screen to load.

Make sure the time is set according to local time zone before executing a cryotherapy procedure, as explained in 5.2.6.4.

Figure 36: The Main Menu screen

5.2.4 Cryohandle

The cryohandle allows the user to easily and safely handle the cryoprobe. It also allows for several operational functions. The cryohandle parts are detailed in Chapter 3 - System description.

5.2.4.1 Using the cryohandle

- **Action button** – this is a blue button on the inner side of cryohandle. It activates/deactivates the freeze cycle and confirms actions displayed on the screen with a blue circle icon:

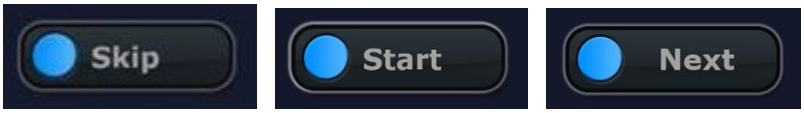


Figure 37: The Action button as displayed on screen (several of the options)

- **Light status indicator** – This is a **BLUE** LED which lights up around the Action button indicating the activity of a freeze cycle.
- **Active warm button** – this is a red button on the cryohandle. It activates the active warm process for fast and safe probe extraction from the target tissue. The active warm process can also be activated from the screen when displayed as a red circle icon (see figure below).

Figure 38: The active Warm button as displayed on screen

5.2.5 Show Last Treatment

The last treatment will be displayed by choosing “Show Last Treatment” icon on the Main Menu screen. This will open the next screen:

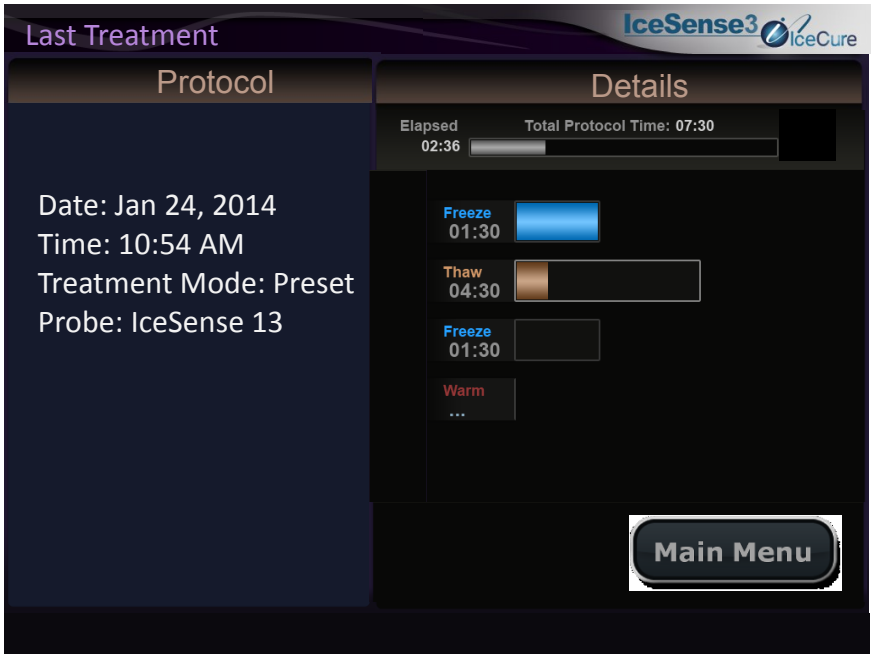


Figure 39: Last Treatment screen

In this screen you can see details of the last procedure that was performed including date, time, treatment mode, probe type and duration of treatment.

5.2.6 General settings

The system general settings and technician mode is available by choosing the “Settings” button on left lower corner of the touch screen (Fig. below).

Figure 40: Activating the Settings option from the Main Menu screen

Choosing the “Settings” button (green arrow) will load the settings screen with four icons representing different options. Pressing any of these icons will open a new settings screen pertaining to that option.

Figure 41: The Settings screen

5.2.6.1 Change workflow

IceSense3™ cryoablation system supports 2 alternative workflows, allowing the user to select a treatment protocol before preparing the system (filling Nitrogen, connecting probe, and testing it) or to prepare the system first and then select a treatment protocol.

To set the preferred workflow, press Settings (in the main menu), followed by “Change Workflow”. Select the preferred workflow and press Back.

Choosing the “Change Workflow” icon will load the screen below enabling two workflow alternatives: users can either Select Treatment mode first then Prepare System for use, or Prepare System for use then Select Treatment mode.

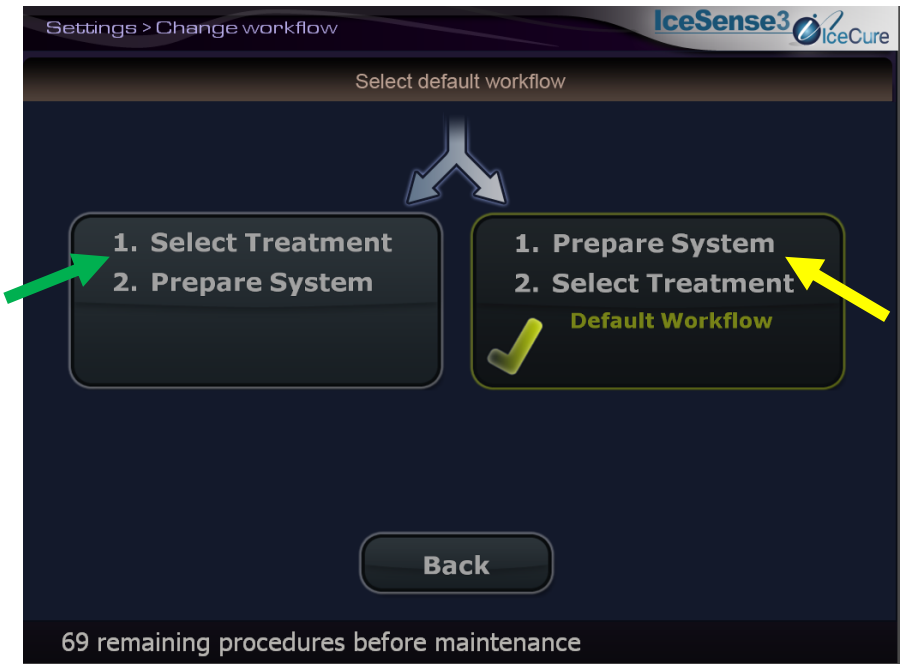


Figure 42: The Change Workflow screen with two alternative workflow settings

5.2.6.2 Log-in to Technician mode

Choosing the “Technician Mode” icon will load a Technician Mode entry screen that is used for maintenance of the system. The technician mode can only be accessed by an IceCure Medical authorized technician and is restricted by a password.

Warning

Never enter the Technician mode screen. Only an IceCure technician or authorized representative is allowed to use the technician mode for maintenance or repair of the system.

5.2.6.3 Export Log

This screen allows you to export any procedure data to a USB removable storage device in an easy and convenient way. When you press the Export Log icon, a popup window appears with the following message:

Connect a USB flash drive and press OK

Press OK to export the log file to the USB drive

Press Cancel to return to Settings screen

If export fails, the message in the status area reads: ***Export failed; make sure a flash drive is connected.***

Before using a flash disk check that it contains enough free space for file storage.

5.2.6.4 Set time

This screen allows you to set the date and time.

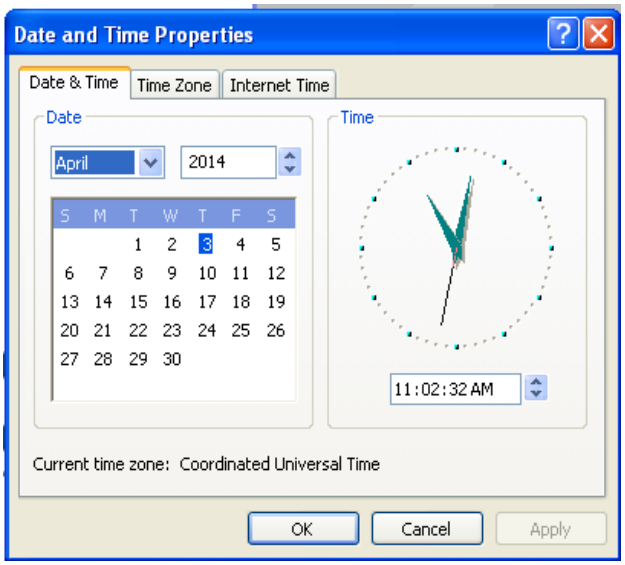


Figure 43: The Windows™ Date and Time Properties screen

Set the date and time according to your time zone and approve it by clicking “Apply” in the right lower corner of the screen. In order to complete the process, restart the system.

Caution

Make sure the time is set according to local time zone before executing a cryotherapy procedure.

5.2.7 Preparing the system for treatment

The system will guide the user through a system preparation process; following the system instructions is essential. Preparation includes technical steps and tests to make sure the system is ready for a cryotherapy procedure. It includes:

1. Dewar refilling and replacement

2. Maintain Sterility (Use of sterile sleeves)
3. Cryoprobe registration and connection
4. System tests

To prepare the system for treatment, choose the option “Prepare for Treatment” in the Main Menu as shown in the below figure.

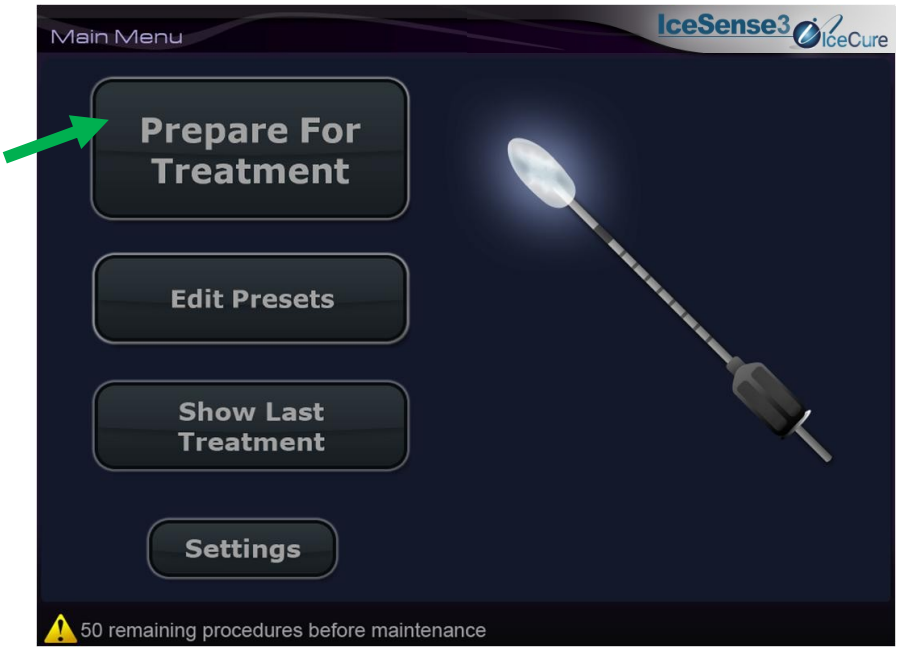


Figure 44: Preparing the system for treatment by pressing “Prepare for Treatment” (green arrow) on Main Menu screen

5.2.7.1 Dewar

Prepare the Dewar for treatment as per the following instructions and as detailed on the system screen (see Fig. below).

Figure 45: The Dewar preparation screen

Filling the Dewar

Caution

Follow the detailed instructions on open the Dewar storage- when you want to replace a Dewar.

- The Dewar must be completely filled prior to each procedure.
- The Dewar must be completely filled prior to each refill.
- The Dewar should never be stored with liquid nitrogen inside the system at the *end* of the working day.
- For proper handling in order to ensure safety, please follow the cryogen supplier instructions.

Warning

Liquid nitrogen may cause serious injury or burn if handled improperly. Local laws and safety rules regarding liquid nitrogen Dewars should always be observed. Maintenance of liquid nitrogen Dewars should be performed by authorized personnel only.

- Check that the Dewar is fully filled (see the arrow on the screen) and cover it with its sponge lid to transfer it back to the system.
- Check there is no frost on the Dewar after you filled it.
- In the event that a Dewar is damaged, use another Dewar to continue the procedure.

Warning

Do not use a liquid nitrogen Dewar if it is damaged.
You can tell that a Dewar is damaged if after filling it, frost appears on the outer wall of the container. Return the Dewar to IceCure technician or an authorized distributor for inspection

Warning

Do not transfer a Dewar with Liquid nitrogen unless it is covered with its designated lid.

- Take off the lid and place the Dewar in its position into the system.

Warning

Removing the Dewar, or placing it back within the system after refilling it must ONLY be done according to system instruction and with the carriage in the bottom position. If the carriage is not in the bottom position, liquid nitrogen may spill out.

- Close the compartment door and press the “Action” button on the cryohandle or “Next” on the screen.

Dewar door is open

If the system detects that the Dewar compartment door is open when it tries to move the Dewar carriage up or down, the following popup message will appear:

Dewar door is open. Close the door to continue.

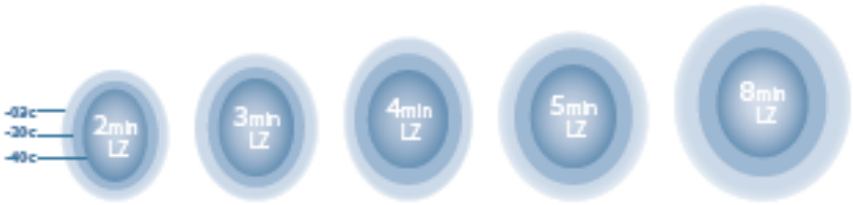
5.2.7.1 Sterile sleeves

After filling the Dewar and placing it in its compartment, please work within sterile conditions. Cover the touch screen and flexible hose with the suitable single-use sleeves, and the cryoprobe holder with a single-use cover to ensure sterility.

5.2.7.2 Cryoprobe Selection

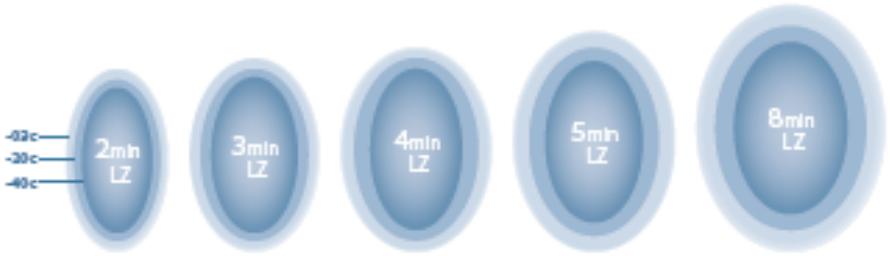
Select a cryoprobe according to your clinical judgment and target tissue.
The iceball size is a function of the freezing time and is also affected by the tissue and blood flow.
Large probe creates oval iceball while small probes creates rounder iceball
Always monitor the iceball growth with adequate imaging techniques.

2.4 SHORT



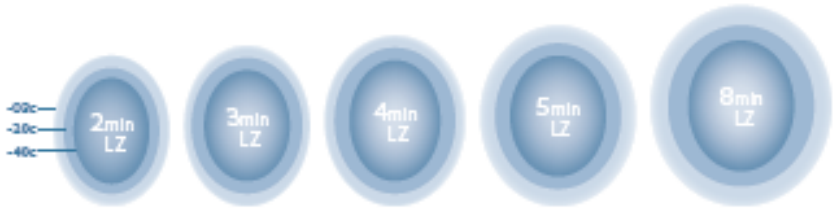
	-3°C			-20°C			-40°C	
	Length (mm)	Diameter (mm)		Length (mm)	Diameter (mm)		Length (mm)	Diameter (mm)
FAP7600000 (2.4 Short)								
2 min	24	20		20	16		17	12
3 min	27	23		22	18		18	14
4 min	30	24		24	20		18	15
5 min	31	28		25	22		19	16
6 min	32	30		26	23		20	16
8 min	36	33		27	24		20	17
10 min	38	35		29	26		21	17
15 min	42	39		31	29		21	19

2.4 LONG



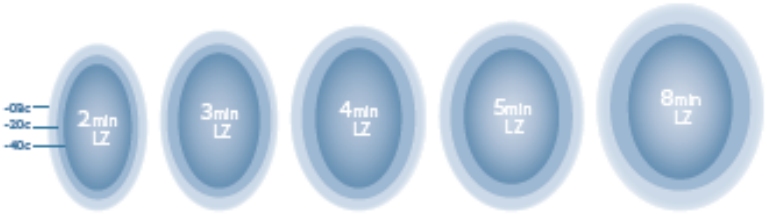
	-3°C			-20°C			-40°C	
	Length (mm)	Diameter (mm)		Length (mm)	Diameter (mm)		Length (mm)	Diameter (mm)
FAP7800000 (2.4 Long)								
2 min	34	19		30	16		27	13
3 min	36	24		32	20		29	16
4 min	38	28		34	23		30	17
5 min	41	30		35	24		30	18
6 min	43	32		36	26		31	19
8 min	46	35		38	28		32	21
10 min	47	38		39	30		33	22
15 min	51	46		39	34		31	24

3.4 SHORT



	-3°C			-20°C			-40°C	
	Length (mm)	Diameter (mm)		Length (mm)	Diameter (mm)		Length (mm)	Diameter (mm)
FAP7100000 (3.4 Short) FAP7300000 FAP7500000								
2 min	30	23		25	19		21	15
3 min	32	25		27	22		22	17
4 min	34	28		29	24		24	18
5 min	36	31		29	25		24	19
6 min	38	33		31	27		25	20
8 min	40	36		32	29		26	21
10 min	43	38		33	30		27	22
15 min	48	44		36	33		28	24

3.4 LONG



	-3°C			-20°C				-40°C	
	Length (mm)	Diameter (mm)		Length (mm)	Diameter (mm)			Length (mm)	Diameter (mm)
FAP7200000 (3.4 Long) FAP7400000 FAP7410000 FAP7700000									
2 min	37	22		32	18			28	15
3 min	40	26		34	23			30	18
4 min	41	30		36	25			31	19
5 min	42	32		36	27			30	21
6 min	46	35		38	29			32	23
8 min	46	37		37	31			32	23
10 min	48	41		38	33			33	25
15 min	52	46		41	36			35	26

Figure 46: Iceball isotherms of IceSense3 cryoprobe from experiments in gel at room temperature.

5.2.7.3 Cryoprobe registration

Identify the cryoprobe serial number (S/N). It appears on the cryoprobe package and on the cryoprobe plastic grip as shown in the figure below.

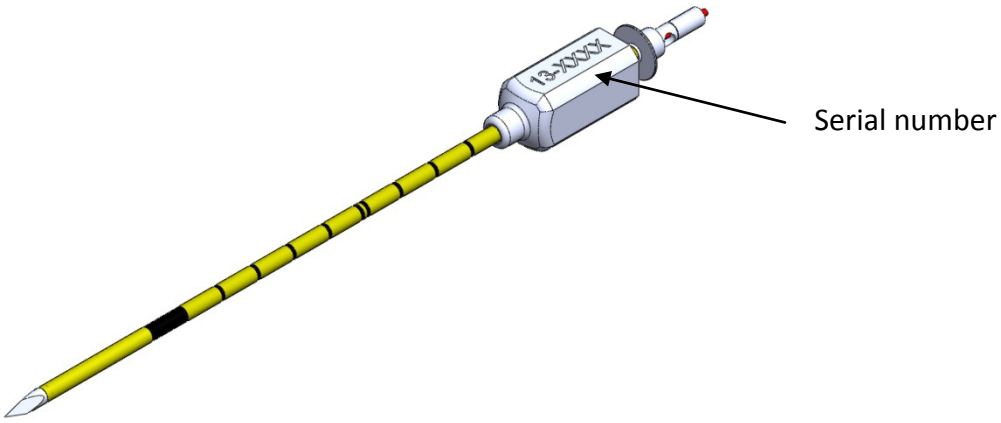


Figure 47: The cryoprobe (the figure is for illustration only)

Enter the serial number of the cryoprobe using the number icons on the screen.

When done, confirm the number is correct and press the Action button on the handle or “Next” on the touch screen.

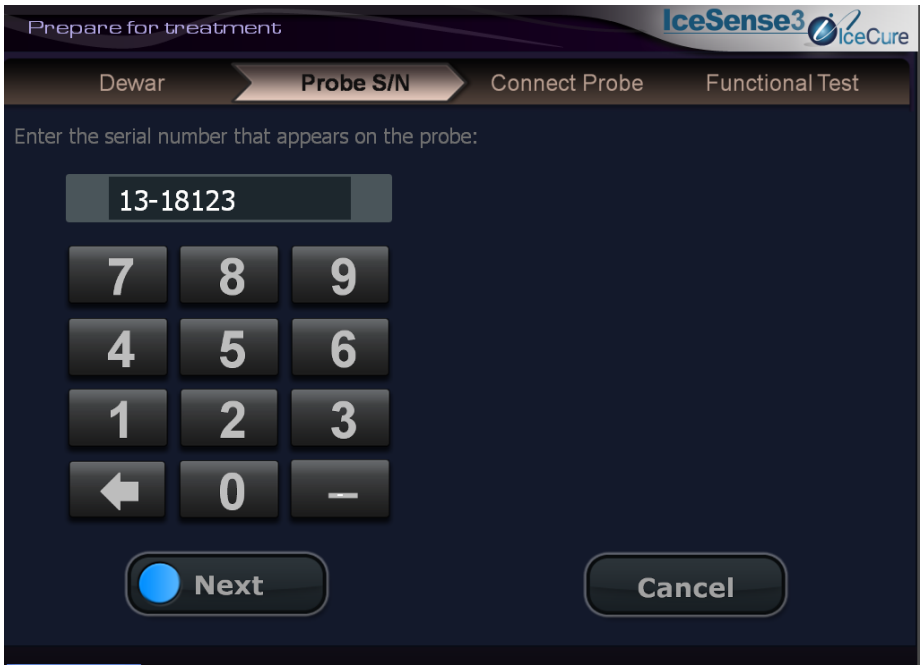


Figure 48: Cryoprobe registration screen

Caution

Verify cryoprobe S/N registration by double checking the serial number on the package and on the cryoprobe itself. Entering an incorrect cryoprobe S/N registration will result in probe nullification.

5.2.7.4 Cryoprobe connection

Connect the cryoprobe to the cryohandle as follows, while maintaining sterility of the probe:

- Remove the plug that covers the probe connection point.
- Insert the cryoprobe into the insertion point in the handle as shown on screen and screw it until a “Next” button appears on screen then confirm screwing by an additional slight rotation to confirm that probe connection is secured.
- Remove the probe cover that protects the tip.
- When done, press the Action button on the handle or “Next” on the touch screen.

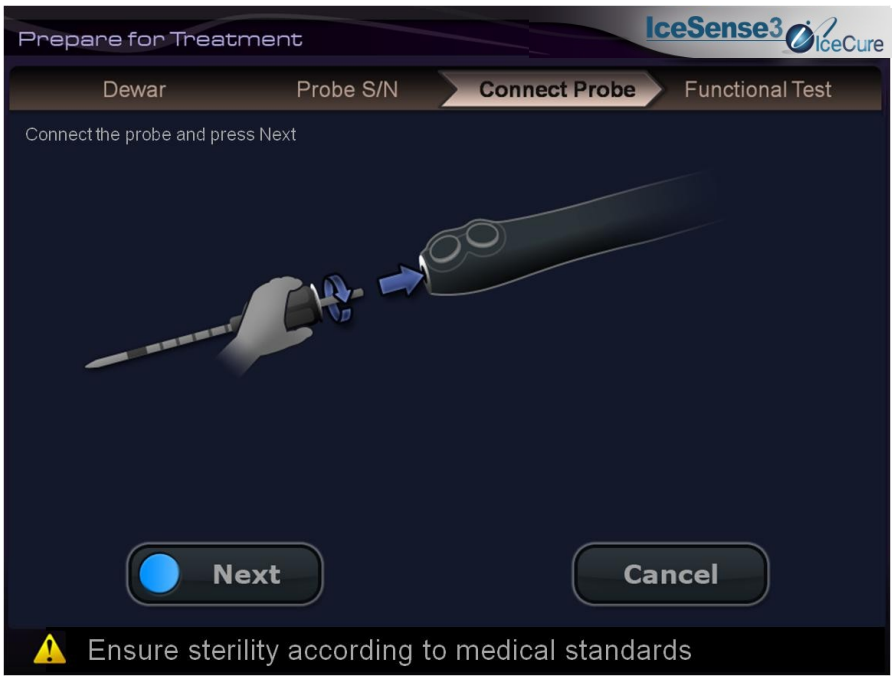


Figure 49: Cryoprobe connection screen

Warning
Never reuse a single-use cryoprobe or a single-use sterile sleeve.

Warning
Never “unscrew” the cryoprobe if you are not clearly allowed to unscrew or disengage it.

- After pressing Next, a “Do not disconnect” message will appear

Warning
After completion of treatment of a given patient, make sure that the single-use cryoprobe and single-use sterile sleeve are removed and discarded.

Warning
Before beginning treatment of a new patient, you MUST ensure that the previous single-use cryoprobe and sterile sleeve have been removed.

Warning
Cryoprobes are fragile and can be damage if mishandled. Do not use a cryoprobe that has been bent, dropped, hit against a hard surface or compromised in any manner, as internal damage to the cryoprobe may have occurred.

5.2.7.5 System test

Perform a functional test to ensure system efficacy and safety per the following instructions and per the screens presented in the figures below:

- Prepare a container full of **sterile** water/saline.
- Insert the cryoprobe into the container and press the Action button on the handle or “Test” on the touch screen.

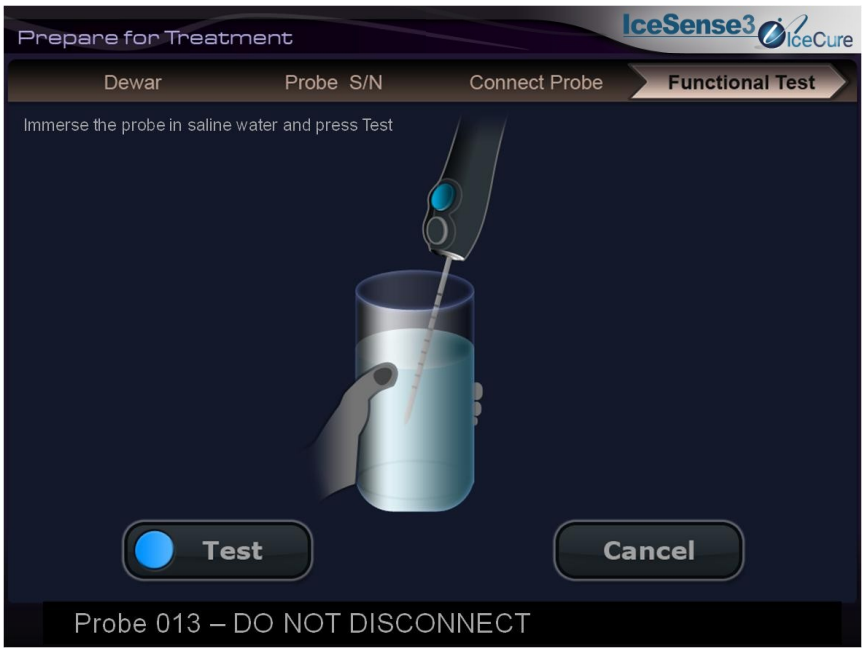


Figure 50: Functional test screen

- The system will check essential parameters.
- A failure of any internal test will result in, an error message displayed on screen. Please record the error number and follow system instructions until you are requested to remove the probe safely from the cryohandle. You will then be returned to the Main Menu screen. Contact IceCure Medical technical service.

  After successful internal test, the system will display the visual inspection screen. You will be prompted to inspect the following:

  - The cryoprobe tip – make sure a small ice ball forms.
  - The cryoprobe shaft – check that there is no ice on it.
  - The saline – check that there are no bubbles.
- Illustrations of potential functional failures will appear on screen. Please refer to these illustrations while inspecting the cryoprobe.

Figure 51: Functional test - visual inspection screen

- If a functional problem occurs or there is any unusual appearance (such as frost on the plastic cover near the cryohandle, foam or any unusual appearance) and it is not represented by one of the Illustrations, press "Cancel". Follow system instructions until you are required to safely remove the probe from the cryohandle. You will then be returned to the Main Menu screen. To start again Check that the Dewar is full and replace the probe. If the problem recurs, do not proceed with treatment. Turn off the system and contact IceCure Medical.
- If a functional problem occurs as represented by one of the pictures, press on the relevant picture.
- Follow system instructions until you are required to safely remove the probe from the cryohandle.
- You will then be returned to the Main Menu screen. Check that the Dewar is full and replace the probe and start again. If the problem recurs do not proceed with treatment. Turn off the system and contact IceCure Medical.
- Choosing ”Success” will load the treatment selection screen.
- If for any other reason you decide to stop the procedure, press “Cancel”. Follow system instructions until you are required to safely remove the probe from the cryohandle. You will then be returned to the Main Menu screen.

Warning

In case of frost on shaft, start active Warm if possible. If not, wait for passive Thaw. In both cases use skin protection techniques.

Warning

During pre-test, portions of the cryoprobe other than the freeze zone, including the plastic cover that is located near the cryoprobe handle, may become cold due to malfunction. If unwanted freezing occurs, stop the pre -test process by pressing "Cancel".

Warning

Pay attention to the probe during pre-test: bubbles, leak or frost on shaft may signal internal problems that could be hazardous.

5.2.8 Treatment Selection

The system allows you to choose between manual mode and automatic mode using preset protocols.

To choose automatic mode, select one of the preset protocols from the Treatment Selection screen as shown below.

Type of treatment is determined by the number and duration of freeze and thaw cycles, and depends also on the practitioner's preferred way of work.

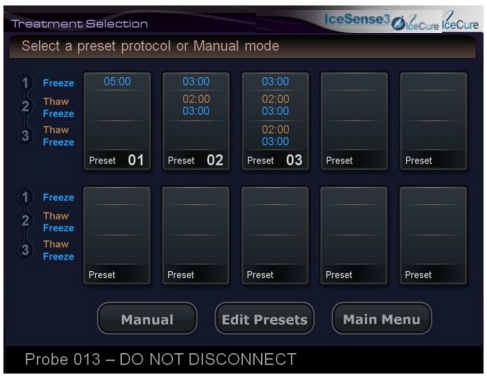


Figure 52: Treatment Selection screen

5.2.8.1 Automatic freeze mode

Each preset protocol icon displays the number and duration of freeze and thaw cycles as shown in Fig. above. Select a protocol by pressing the desired icon on the touch screen. A procedure screen will open. After inserting the cryoprobe into the tissue, you will be able to start the cryoablation procedure.

5.2.8.2 Define treatment protocols

IceSense3™ cryoablation system allows you to define specific treatment protocols by pressing the "Edit Presets" icon at the bottom of the Treatment Selection screen or in the Main Menu screen.

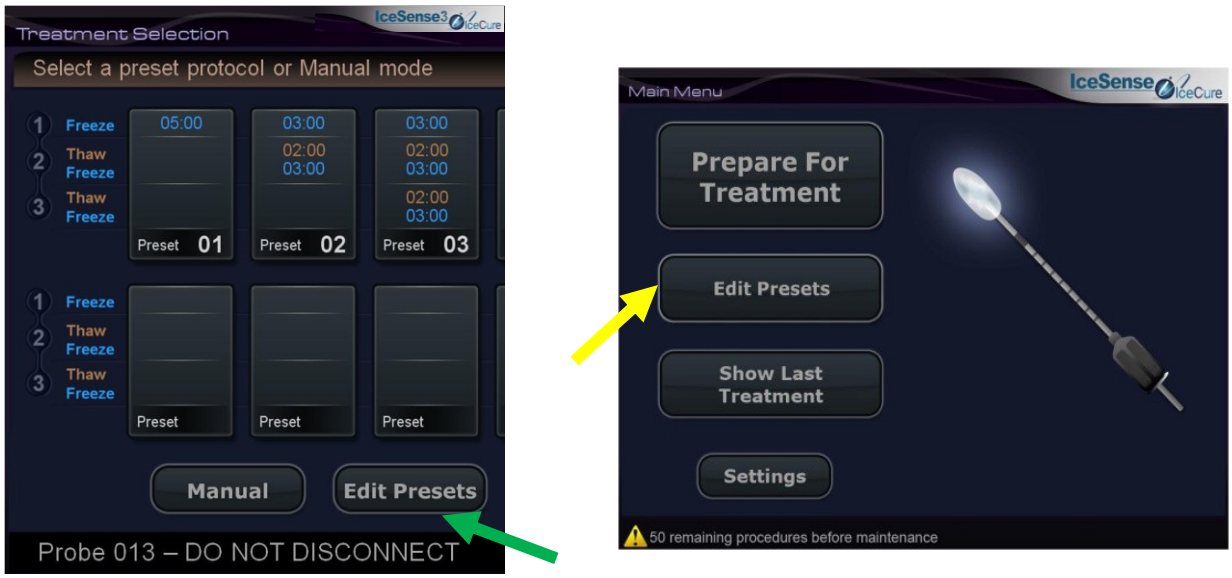


Figure 53: Define a treatment protocol by choosing Edit Presets on the Treatment Selection screen (green arrow) or in the Main Menu screen (yellow arrow)

Choosing either option will open the "Preset Setup" screen and you will be able to add a specific protocol by pressing one of the empty Preset icons, or edit an existing protocol by pressing one of the pre-defined Preset icons.

Figure 54: Editing an existing protocol (green arrow) or adding a new one (yellow arrow)

5.2.8.3 Adding a protocol

If you choose to add a protocol, press one of the empty slots in the screen: the "Edit Preset" screen will load.

Please follow the next steps:

1. Choose the number of freeze cycles in the upper left corner of the screen.

2. Decrease/increase the time for every cycle using +/- icons. Each step will increase/decrease 15 seconds of the cycle time.
3. Save the protocol by pressing the “Save” icon.

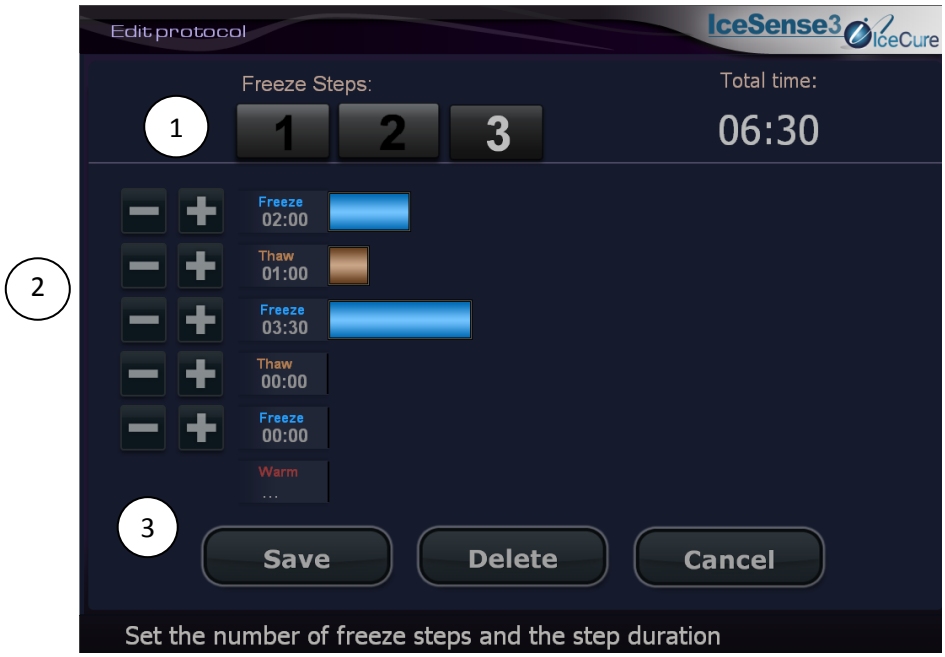


Figure 55: Steps for adding a protocol

5.2.8.4 Editing a protocol

If you choose to edit an existing protocol, the “edit preset” screen will load.

The process is very similar to that of adding a new protocol.

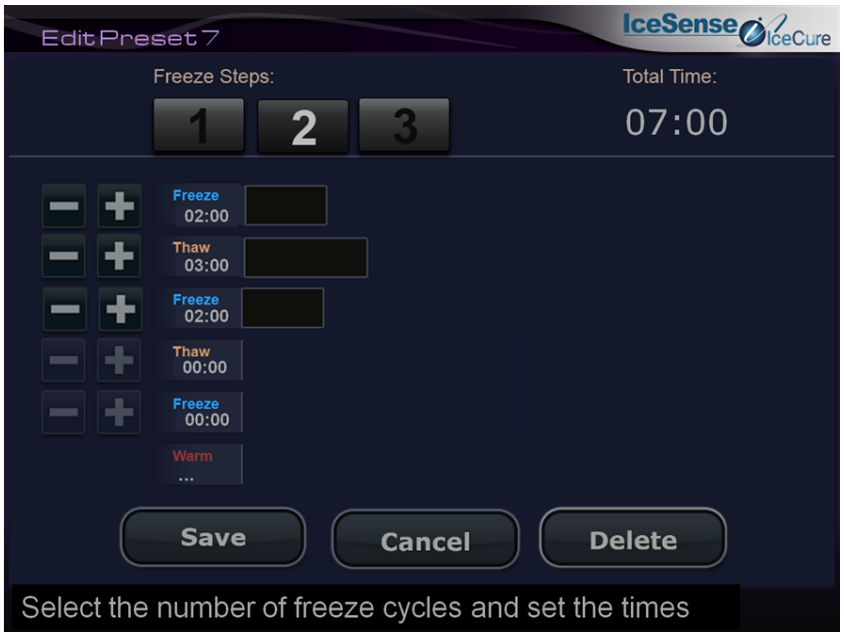


Figure 56: Edit Preset screen

5.2.8.5 Manual freeze mode

The manual freeze mode allows you to perform a cryotherapy procedure without setting its duration or the number of freeze-thaw cycles in advance. You can choose manual freeze mode by pressing the "Manual Mode" icon at the bottom of the "Treatment Selection" screen.

Figure 57: Choosing the Manual Mode option (green arrow)

5.3 Operational stages

5.3.1 Safe Operation in Percutaneous Procedures

When performing percutaneous cryotherapy procedures, meticulous observation of the incision site and the skin overlying the treatment site is required. Skin protection techniques must be implemented to avoid thermal injury to the skin.

Skin protection techniques include, but are not limited to: dripping room-temperature sterile saline on these areas; continuous monitoring of the growing ice ball by ultrasound; utilizing an external thermocouple to measure skin temperature; injecting sterile saline or local anesthetic between the skin and the ice ball formation; and placing moist gauze between the skin and the cryoprobe.

5.3.2 Preliminaries

Before operating IceSense3™ cryoablation system, make sure you have completed all pre-operational stages.

Warning

Insertion of the cryoprobe into the target tissue is performed under the guidance of an appropriate imaging device and by an authorized practitioner trained by IceCure medical.

Warning

You must NOT allow the freeze process to start before the cryoprobe tip is actually within the target tissue.

Before activating the freeze cycle, insert the cryoprobe into the target tissue according to the following steps:

1. Plan the trajectory of the probe prior to placement. The center of the cool zone shall be along the longest dimension of the target tissue (if required parallel to the chest wall in breast applications).
2. In percutaneous procedures, insert probe under ultrasound guidance or other appropriate imaging guidance:
    - Confirm longest dimension of the target tissue
    - Perform a 3 mm skin incision (for example using #11 blade)
    - Position the tip of the cryoprobe minimally 4 mm beyond the distal edge of the long axis of the target tissue

For optimal probe positioning please note the following:

Probe size	Center of Cool Zone
Probe 3.4Long	20mm from needle tip
Probe 3.4 Small	12mm from needle tip
Probe 2.4Long	14mm from needle tip
Probe 2.4 Small	10mm from needle tip

The order in which you follow these steps is essential for maintaining sterility and patient safety.

First, insert the probe tip into the target tissue. Be aware of the markings on the probe: the wide mark closest to the tip is the safety mark. In percutaneous procedures i**t must be completely inside the tissue** to avoid skin burns. The rest of the marks indicate depth of probe insertion: each mark equals one centimeter with distinctive markings at 5 and 10 cm as shown in Fig. below.

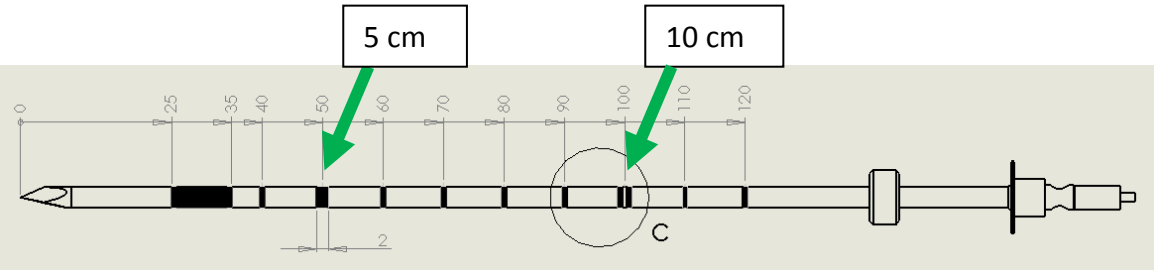


Figure 58: illustration of a short 3.4mm probe Markings on the probe. Main marks indicate safety (thick mark on left), 5 cm (slightly thick third mark from the left) and 10 cm (double mark in circle).

Once you have verified the probe is located in its right place, you may begin freezing.

5.3.3 **Freeze Cycle**

Selecting the type of treatment, Manual or Automatic, is discussed in section 5.1.7.

Warning

Portions of the cryoprobe other than the freeze zone, including the plastic cover that is located near the cryoprobe handle, may become cold and cause tissue damage. If unwanted freezing occurs, immediately stop the freezing process.
To prevent injury, cryoprobes must be closely observed during use for signs of unwanted freezing.

Warning

You must NOT allow the freeze process to start before the cryoprobe tip is actually within the target tissue.

Warning

The practitioner must hold the cryohandle for the duration of the cryoablation procedure.

5.3.4 **Pause Option:**

Pause option is available at any freeze cycle, in Manual or in Automatic mode. The use of the button is according to clinical judgment (for re-positioning the probe in the tissue or injecting saline, for example). Using the pause option should be as minimal as possible. While using the pause button, freezing mode is disabled therefore is not calculated in the total freezing cycle time.

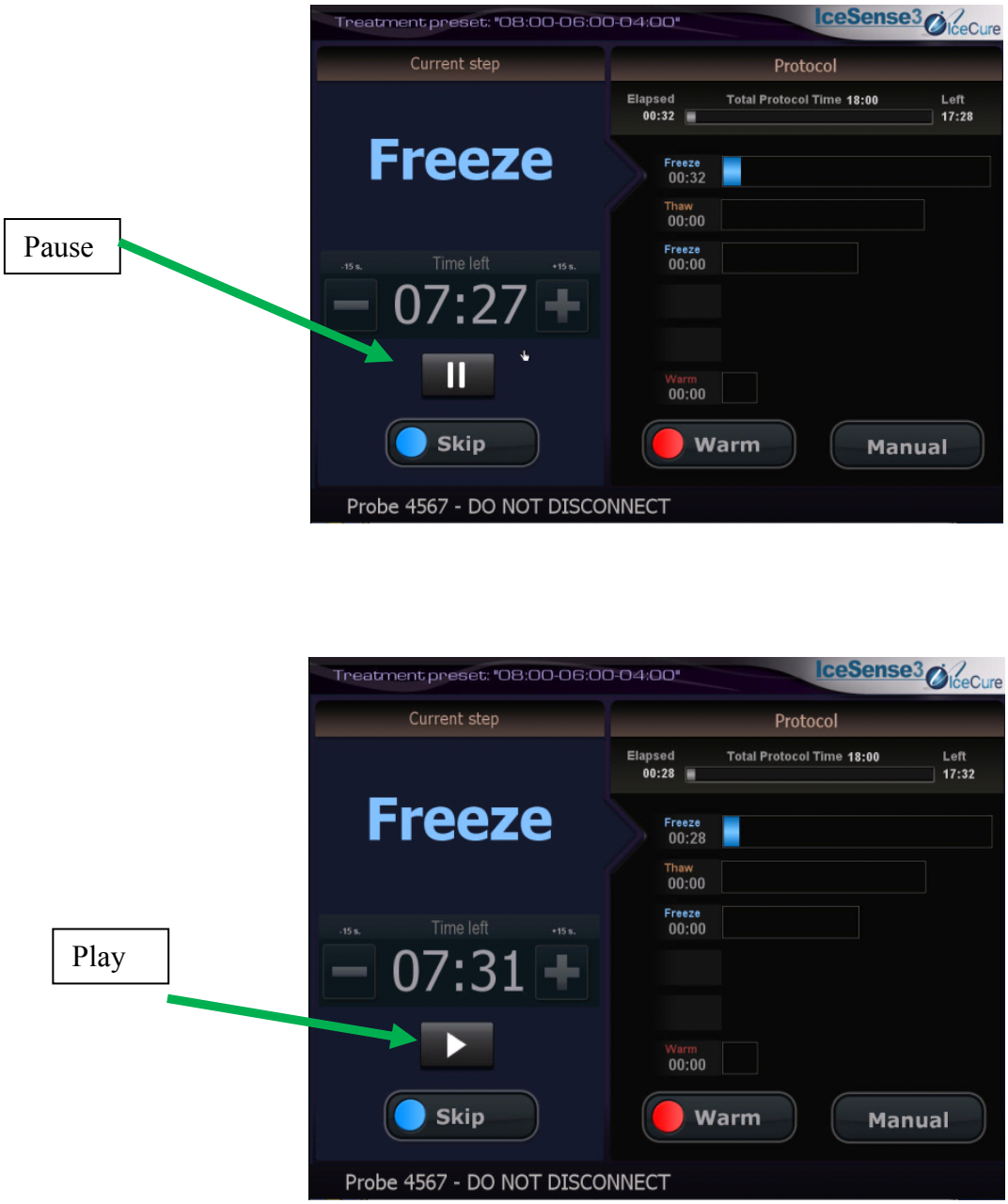


Figure 59: Pause and Play buttons during the freeze cycle.

The pause time does not affect the freeze preprogrammed time but depending on when and how long the pause time is defined it may affect the iceball size.
The physician should always monitor the iceball size during the whole procedure.

IceCure Medical recommends is to use Pause only if necessary.

5.3.4.1 Manual freeze mode

Choosing the Manual freeze mode will open the treatment screen for manual mode as show in Fig. below.

- To **activate** the freeze cycle, press the Action button on the cryohandle and hold it for one second or press the “Freeze” icon on the screen. The **BLUE** LED will light up around the Action button.

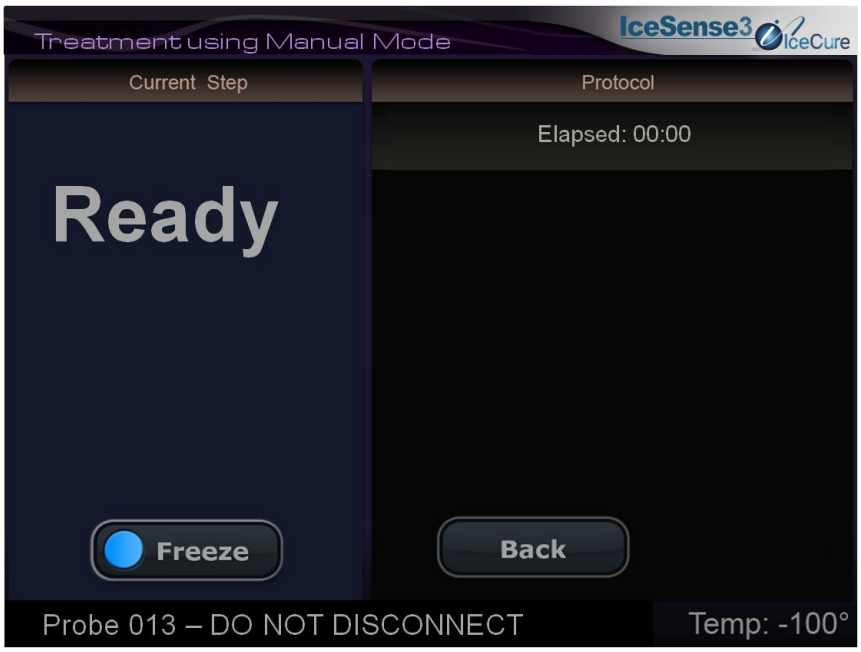


Figure 60: Manual Mode screen: press on Freeze to start the freeze cycle.

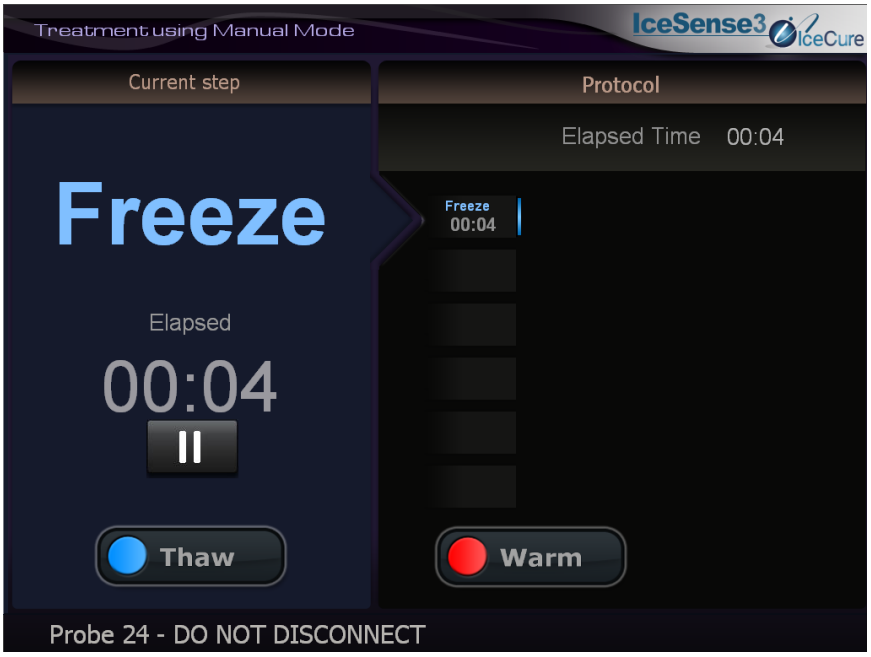


Figure 61: Freeze screen in Manual Mode

- The “Freeze” icon will change to a “Thaw” icon and will allow you to move from freeze cycle to thaw cycle by pressing that icon or the Action button on the cryohandle.

Figure 62: Thaw screen in Manual Mode

- You can continue to move between cycles by the same method.
- To **end** the procedure, press the Warm button on the cryohandle or the "Warm" icon on the screen. Freezing will cease and the Warm screen will open.
  The **BLUE** LED on the cryohandle will turn off.
- Pressing the RED button will start the warming process and will initiate the end of the procedure.

Figure 63: Warm screen in Manual Mode

During the manual procedure the system provides information regarding treatment progress:

- The left side of the screen displays the Current Step (freeze, thaw or warm cycle) and time elapsed for this specific step.
- The right side of the screen displays information on the entire Protocol as total elapsed time and treatment format.
- If you perform more than 3 consecutive freeze/thaw cycles, the right side will only display the last 5 actions due to screen size limitation (3 freeze thaw cycles).

5.3.4.2 **Automatic freeze mode**

Choosing one of the suggested protocols from the Treatment Selection screen will open the automatic protocol screen.

- To activate the freeze/thaw preprogrammed cycles, press the Action button on the cryohandle and hold it for one second or press the “Freeze” icon on the left lower corner of the screen. The **BLUE** LED will light up around the Action button.
- The “start” icon will change to a “Skip” icon.
- The skip icon enables the user to skip from the current step in the cycle to the next step as preprogrammed.
- Within a given protocol, if you want to increase/decrease the preprogrammed time of a cycle when the cycle has already started, use the +/- icons on the left side of the screen to add/subtract 15 seconds with each push.
- At the end of the last freeze step in automatic mode, the Warm step will begin and the Warm screen will be displayed.

- **You can move from the automatic mode AT ANY TIME by pressing the Manual mode button on the screen, without interrupting the procedure. When in Manual, you can’t go back to Automatic mode.**
    - If you do so, proceed as explained in section Manual freeze mode: press the Action button on the cryohandle to move from freeze to thaw and monitor the process under ultrasound.

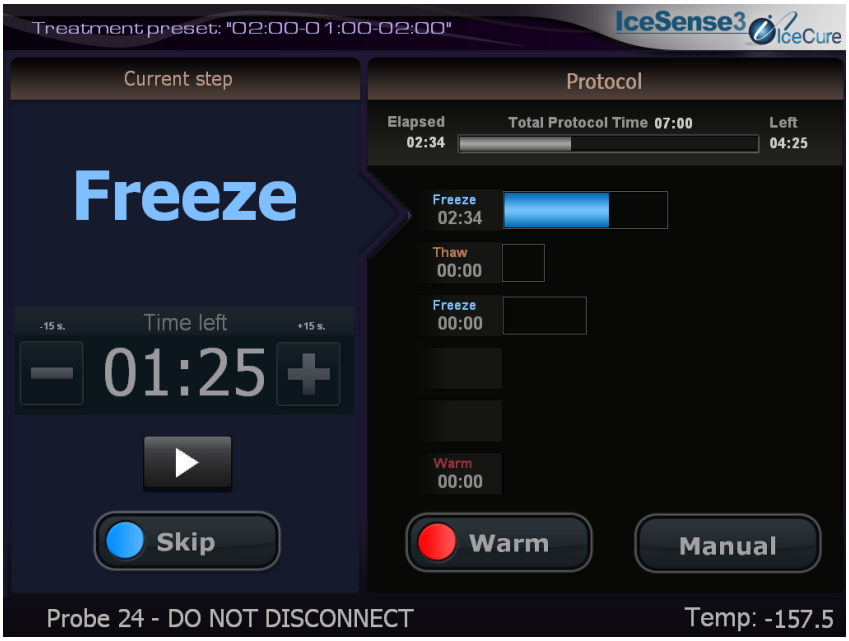


Figure 64: Freeze screen in Automatic mode

During the preprogrammed procedure the system provides information regarding treatment progress:

- The left side of the screen displays the Current Step (freeze, thaw, or warm cycle) and time left for this cycle.
- The right side of the screen displays information concerning the overall Protocol, including total protocol time, time elapsed, protocol format, and changes you have made, if any, to the preprogrammed protocol.

5.3.5 **Thaw**

During Thaw, the iceball melts partially or totally depending on the thaw time and the tissue properties.

It is clinically important to have a thaw cycle between two freeze cycles and to keep the probe location steady in the target tissue during all of the thaw period. Control the process under Ultrasound or any other imaging system.

5.3.6 **Active warm process**

The active warm step occurs at the end of every treatment. Its purpose is to allow the cryoprobe's removal from the target tissue in the fastest and safest way.

- To activate the Active warm, press on the Active warm button on the cryohandle or the "Warm" icon on screen as previously shown.
- The Warm screen will be displayed and a time count will appear.

- At the end of the warm step, a message will be displayed on screen informing the user that the warm cycle is done (for example 40-50 seconds for 2 cm iceball).
- Wait for the message, then gently remove the cryoprobe from the target tissue and then press Finish. Do not force removal of the cryoprobe from the tissue as it might increase the risk of hematoma.
- If the cryoprobe cannot easily be extracted from the tissue, press the Active warm button on the cryohandle or "Warm" icon on screen to initiate another warm cycle.
- After the cryoprobe has been removed from the tissue, press the Action button on the cryohandle or the "Finish" icon on screen to complete the procedure.
- After the cryoprobe has been removed, apply momentary pressure to the insertion site. You may apply adhesive skin closure to the incision and cover it with a 4x4 gauze dressing.
- The system will then perform several verification steps and it will inform you when it is safe to disengage the probe.
- In case the active Warm process isn't available, wait for passive Thaw.

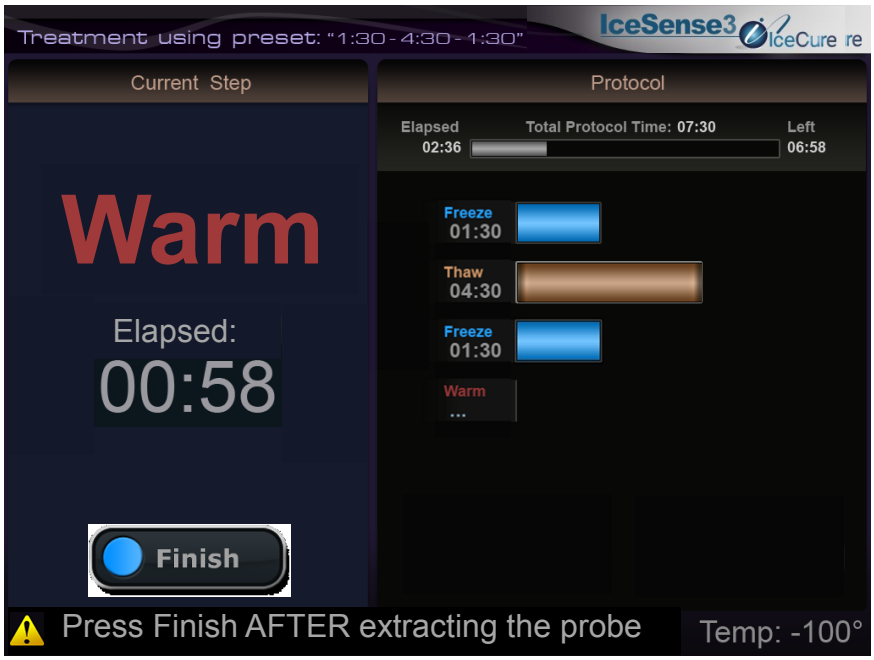


Figure 65: The Active warm screen during procedure

- Instruct patients:
  - To remove gauze dressing after 24 hours; and to expect minimal discharge. Adhesive skin closure should be removed after 7 days if it has not already fallen off.
  - That they may need over-the-counter analgesics for mild discomfort after procedure.
  - That swelling and moderate ecchymosis may be present for several weeks.

Warning

Before removing the cryoprobe from the tissue, make sure the freeze effect has been deactivated and the cryoprobe can be easily withdrawn. Never use excessive force to extract the cryoprobe.

Warning

DO NOT push the warm button when the cryoprobe is not within the target tissue, as skin burns could occur and not before the freezing protocol is completed, unless you want to shorten the procedure due to clinical judgment.

5.3.7 Replace the Dewar during a cryoprocedure

Option to refill the Dewar is available at each Thaw cycle.

In case you intend to do a long treatment that will freeze over *12* minutes, replace the Dewar during the thaw time of the procedure.

First be always ready with an additional full Dewar in case you consider you may need an additional Dewar for a longer freeze time.

- At every Thaw, The system will automatically ask if you want to replace the Dewar: (figure below)

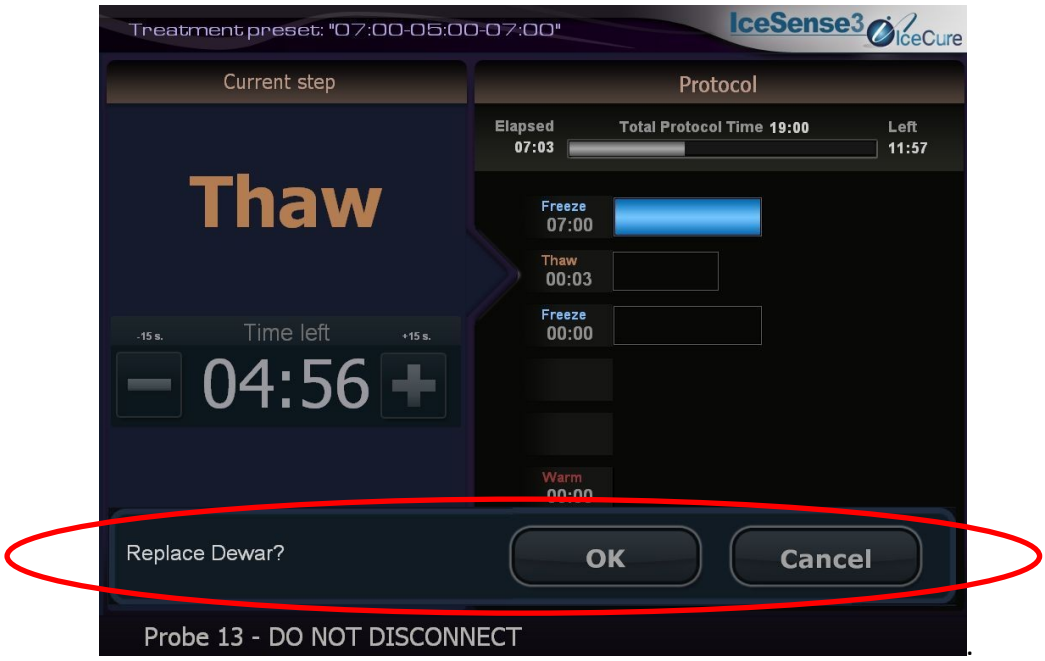


Figure 66: Replace Dewar option question

- If you answer "Cancel", you will stay in the "thaw" screen.
- If you press "OK" you will get the "Lowering the Dewar" message. (figure below)

- If you don’t press either button, the message will disappear shortly before the end of the Thaw cycle.

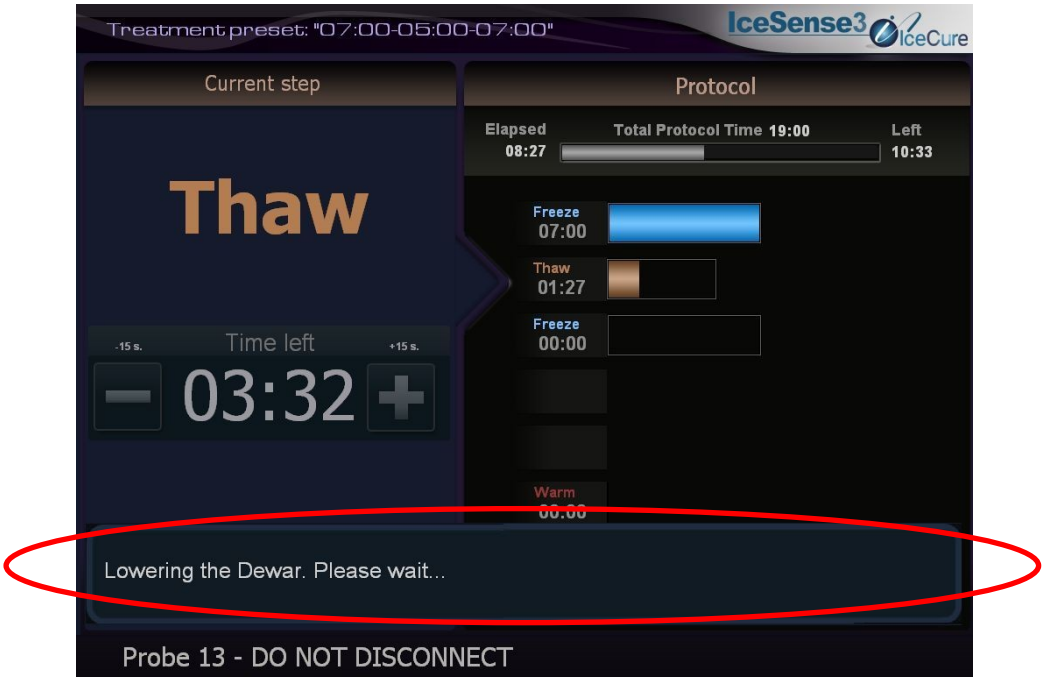


Figure 67: Lowering the Dewar

- The system will perform several steps, then it will inform you that it is safe to replace the Dewar and you will get the "Replace Dewar screen" (figure below)
- Please enter a full Dewar instead of the old one and only then press ok to continue.
- At the same time you will get an interactive update of the thawing time.

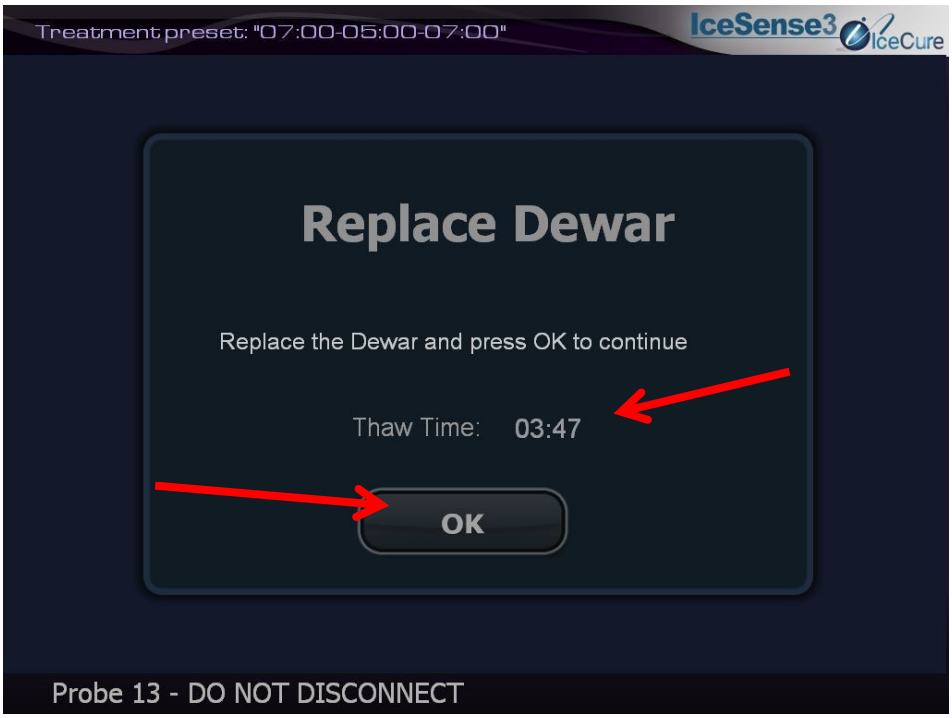


Figure 68: The replace Dewar screen and press ok to continue

- After pressing the 'OK' button, the system will proceed and prepare the new Dewar that was entered. The screen will show "Proceeding, please wait… " (figure below)

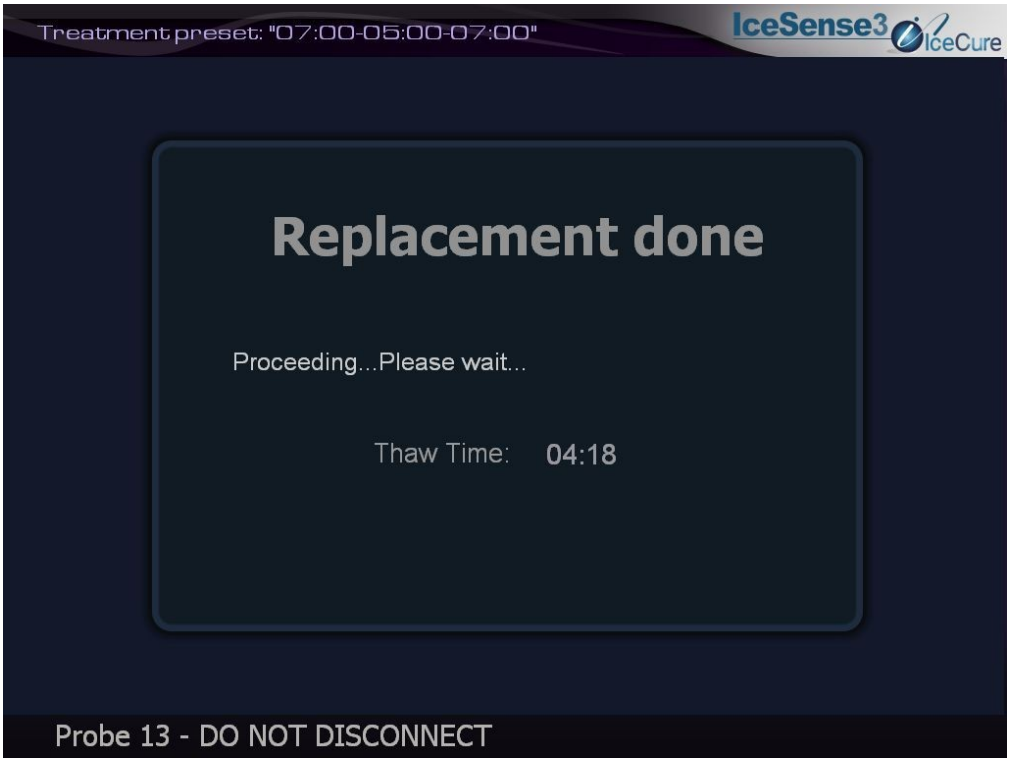


Figure 69: The replacement done follow up screen

- When preparation of the new dewar is complete, the system will come back to the Thaw cycle (figure below).
- **To go to the next freeze cycle, you have to press skip –** even if the time to complete the replacement exceeded the preset Thaw time (figure below).

Warning

If you don't press skip after replacing Dewar, the system will stay in Thaw mode.

Figure 70: Replacement was completed before the Thaw ended

Figure 71: Replacement was completed after the Thaw ended

5.3.7.1 Replace the Dewar during Freeze

In case of low Nitrogen, the system can't continue to Freeze. So it will ask to refill the Dewar in Freeze cycle (see fig. below)

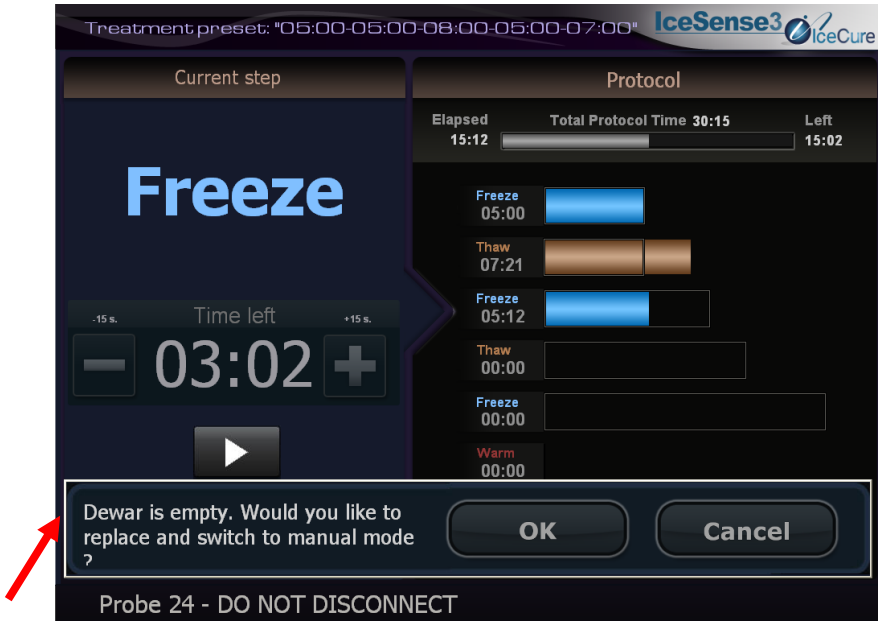


Figure 72: Replacement during Freeze, in case of empty Dewar.

- If you press OK, you can replace a full Dewar and continue the procedure.

When pressing OK, the system will move to Manual mode and be in a Thaw cycle.
Pay attention that in Manual mode, you need to press the icon on the screen for each freeze or thaw cycle.

- Replace Dewar as in paragraph 5.3.7.

- If you press cancel, you will end the procedure (see figure below).

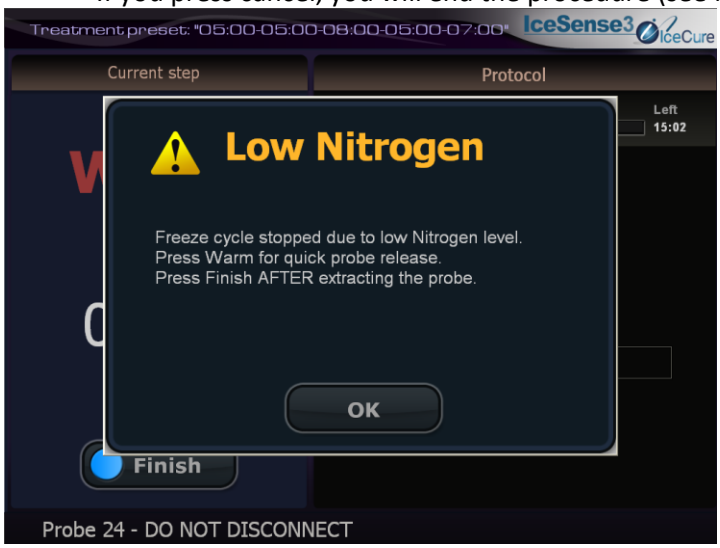


Figure 73: procedure stopped due to Low Nitrogen.

5.4 Post-operational stages

5.4.1 Removing the temperature sensor from tissue

At the end of the cryotherapy procedure the temperature sensor should be removed from the tissue by carefully pulling on it. The extraction should be done only after a passive thaw of a few minutes since the temperature sensor can be surrounded by ice. Removing it too quickly before thawing can damage the target tissue.

Warning

Before removing the temperature sensor from the tissue, make sure the freeze effect has been deactivated and the sensor can be easily withdrawn. Never use excessive force to extract the temperature sensor.

5.4.2 Removing the cryoprobe from the cryohandle

After removing the cryoprobe from the target tissue, and the message that it is safe to disengage the probe is displayed, detach the cryoprobe from the cryohandle as follows:

1. Unscrew the used cryoprobe from the cryohandle and dispose of it appropriately.
2. Remove the single-use sterile cover from the cryohandle.
3. Close the cryohandle with the covering plug.

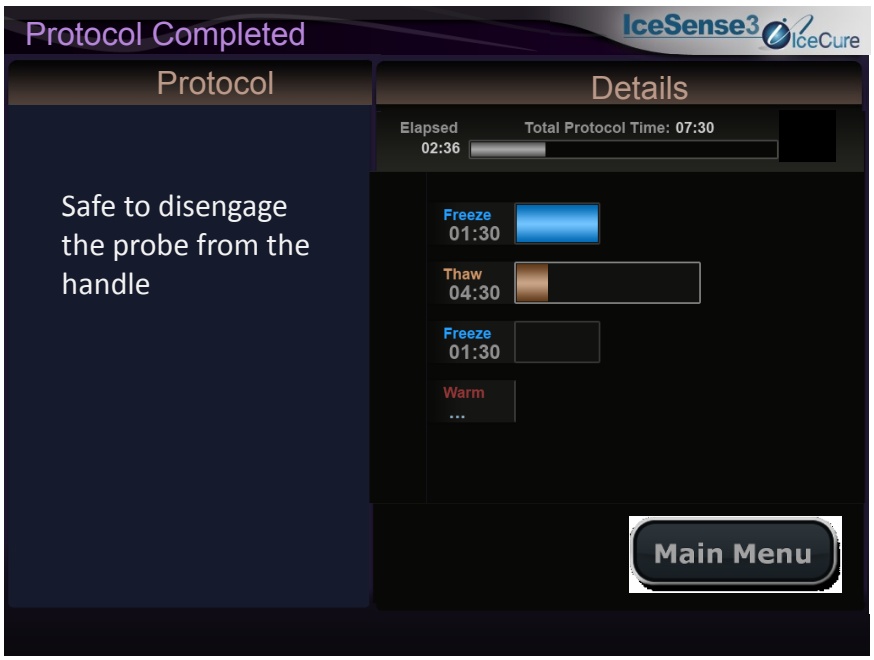


Figure 74: Protocol Completed Screen

Warning

Dispose of the cryoprobe, temperature sensor and cryohandle sleeve in accordance with institutional policy.
Do not reuse, do not resterilize.

5.4.3 Disassembling the temperature sensor

If a temperature sensor was used, pull the gray part of the cable connector backwards to release it, and then pull the cable connector away from the front panel.

5.4.4 Exiting the IceSense3™ cryoablation system treatment mode

At the end of the treatment and after removing and disassembling the cryoprobe and temperature sensor, return to the Main Menu screen by pressing the “Main Menu” icon on the right lower corner.

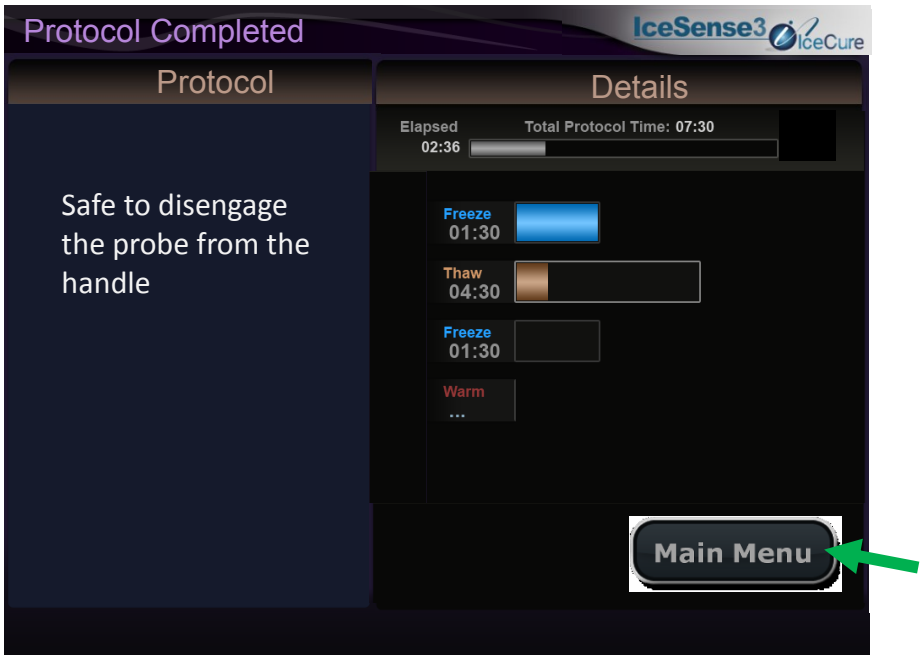


Figure 75: Protocol Completed screen. Pressing on the “Main Menu” icon (green arrow) will load the Main Menu screen.

Figure 76: The Main Menu screen. To exit the system, press on the "Exit" icon (green arrow).

At the end of the last treatment of the day, Switch OFF the mechanical ON/OFF button and unplug the electrical cable. Clean the system following instructions in section 8.1 and move the system to its storage location.

5.5 System failures

5.5.1 IceSense3™ cryoablation system failure

When the IceSense3™ cryoablation system detects an error, the following will occur:

- A **failure message** will appear.
- The procedure will be aborted.

When the above occurs, take action as follows:

1. **Write down the error message and number, follow the system instructions**.

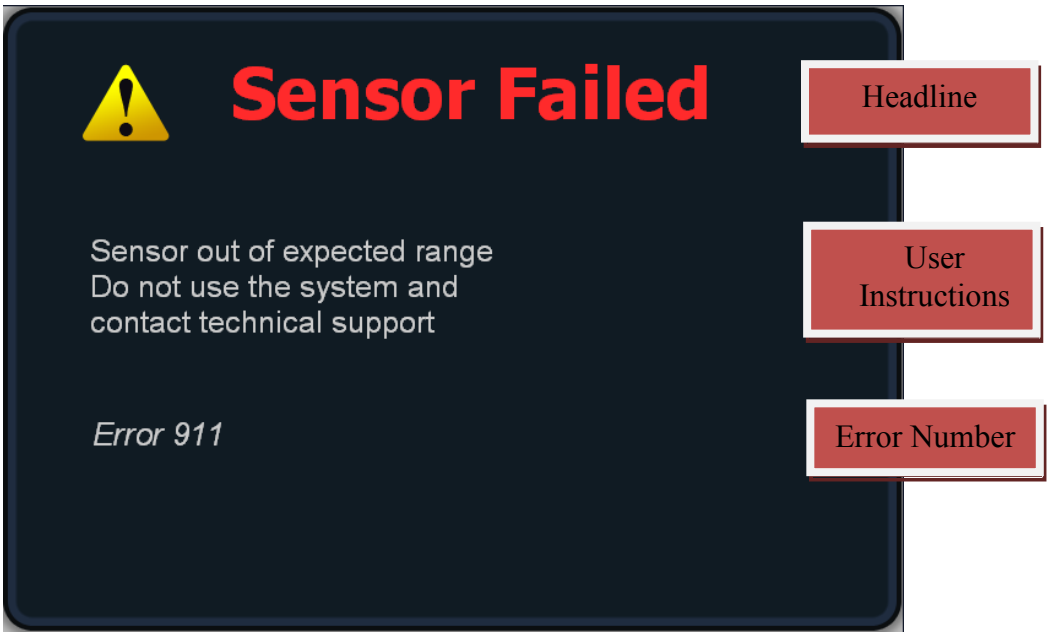


Figure 77: System Fail example screen

2. If you are in the middle of a cryotherapy procedure, **wait for passive thaw** and then carefully **remove the cryoprobe** from the tissue.
3. **Detach the cryoprobe** from the cryohandle ONLY after Dewar the system instructs you that it is safe to do so.
4. If system shut down is required, **shut off the IceSense3™ cryoablation system** by pressing the mechanical ON/OFF button on the main chassis and then remove the plug from the power supply.

5.5.2 IceSense3™ cryoablation system touch screen failure

If the touch screen shuts down, you will need to shut off the system with the mechanical ON/OFF button and remove the plug from the power supply. This will end the cryotherapy procedure.

Warning
In case of software crash, switch OFF the mechanical ON/OFF button and unplug the electrical cable. Call IceCure Medical for technical service before restarting the IceSense3™ cryoablation system.

5.5.2.1 Emergency Stop button

The fastest way to end a procedure is to press the Warm button in the handle or on the screen. However, in case of electrical emergency, press the RED ROUND Emergency Stop button located on the right side of the main chassis. The Emergency Stop button is designed for emergency shutdown of the unit. Pressing this button immediately turns off the system.

Switch OFF the mechanical ON/OFF button and unplug the electrical cable.

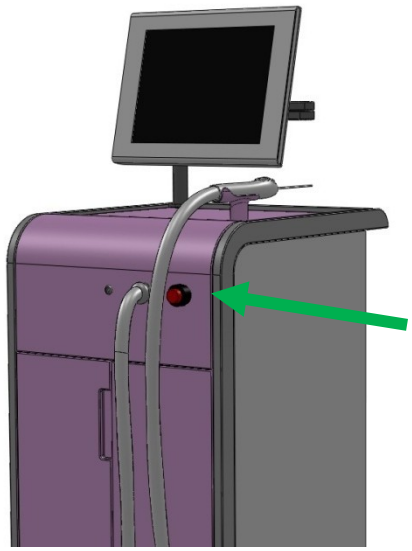


Figure 78: The Emergency Stop button located on the main chassis (green arrow)

Warning

If an electrical hazard is detected at any time, PUSH the Emergency Stop button immediately.

Caution

Push the Emergency Stop button ONLY when there is NO other choice. Wherever possible, the system should be shut down by the standard procedure. Excessive use of the Emergency Stop button may damage the system.

After pressing the emergency stop button, wait for "passive thaw" before extracting the cryoprobe from the tissue.

To release the Emergency Stop button, turn it clockwise.

If emergency stop button was *accidently* pushed, the procedure is cancelled but can start again with a new probe.

6 COMPUTER INTERFACE

6.1 The technician menu

The technician menu/screen can be accessed by pressing the setting icon on the left lower corner of the main menu screen and then pressing the Technician icon.

The technician mode can only be accessed by an IceCure Medical authorized technician and is restricted by a password. It is used for maintenance of the system.

Warning
Never enter the technician mode screen. Only an IceCure technician or an authorized representative can access this mode for maintenance or repair of the system.

6.2 Reading the screen

The screen within the control panel is represented by the picture below:

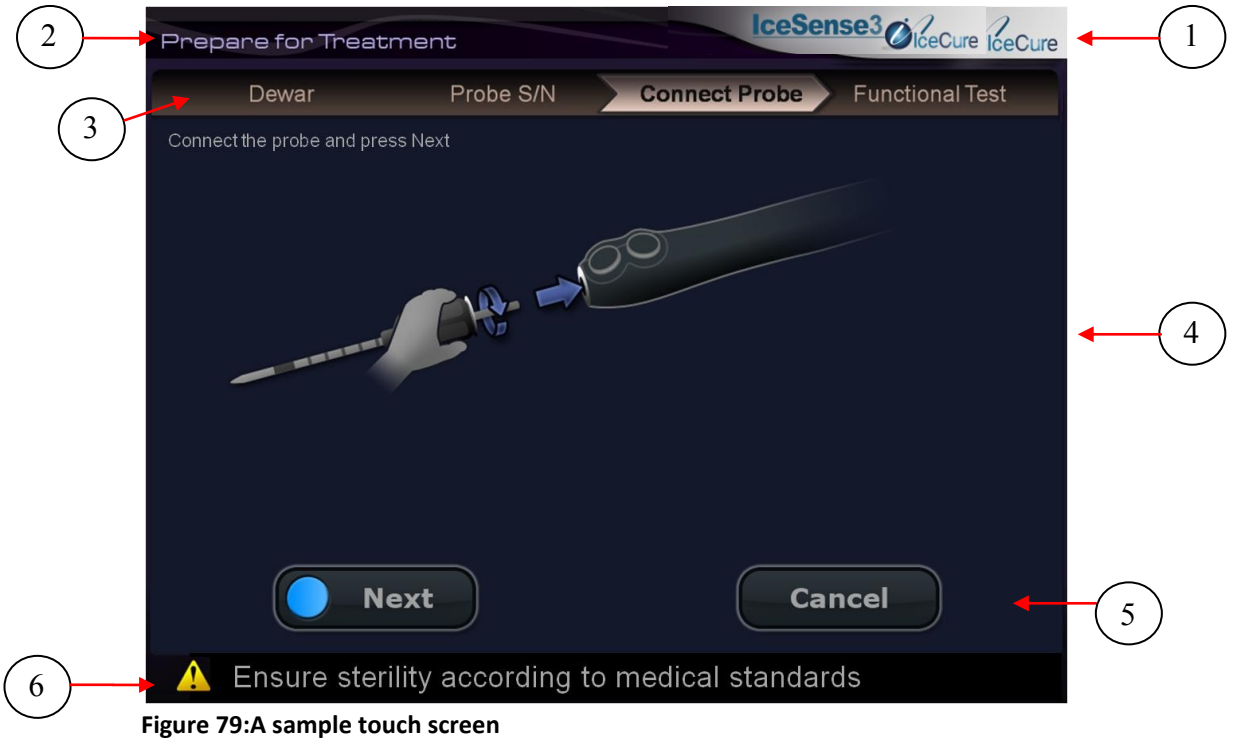


Figure 79:A sample touch screen

6.2.1 Parts of the Screen

The following key defines the numbered parts of the above figure:

1. Logo bar

2. System mode
3. Wizard/Instruction bar
4. Main interaction area
5. Icons
6. Status display

6.3 System messages

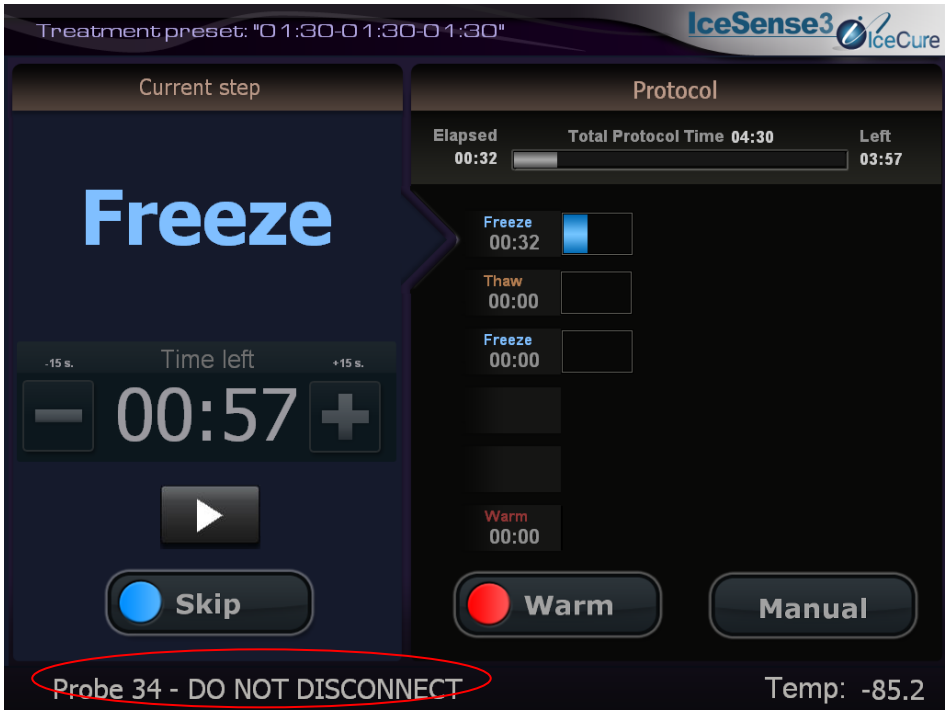
Messages can appear in one of three modes: status, warning or error messages.

6.3.1 Status messages

Information that is valuable to the user will appear in the status bar area at the bottom of the screen.

External temperature sensor readout will be displayed in the right bottom corner.

Other status messages, such as the type of cryoprobe currently connected will be displayed in the left bottom corner. For Example:



Status message

Figure 80: Status message example

6.3.2 Warning messages

Critical information will appear as a pop-up dialog with an “OK” button for acknowledging the message.

If a warning message appears during a treatment, it will appear in the following format:

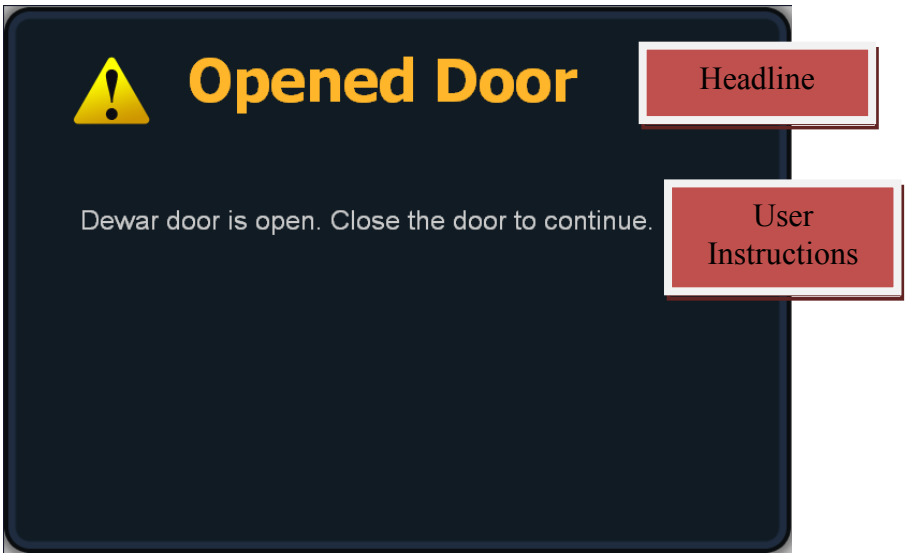


Figure 81: Warning message format example

6.3.3 Error messages

Information that prevents the user from continuing the operation of the system will appear as a dialog box that cannot be closed, stating the problem and possible solutions.

When such a message appears, the user should carefully follow system instructions.

If an error appears during a treatment, it will appear in the following format:

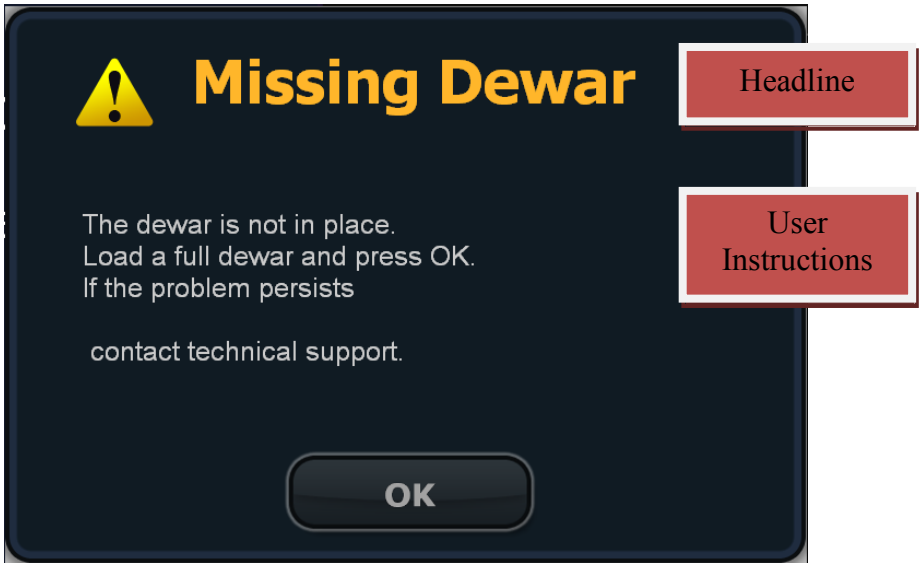


Figure 82: Error message format example

Pressing the OK button will indicate you have read this message and will dismiss this popup.

Warning

When the system shuts itself down due to an error, contact IceCure Medical and describe the error message shown on the screen as precisely as possible. Do not attempt to reuse the system before contacting IceCure Medical. After reporting or making note of the error message, switch OFF the mechanical ON/OFF button and unplug the electrical cable.

7 ACCESSORIES

7.1 Cryoprobe

7.1.1 Single use sterile cryoprobe

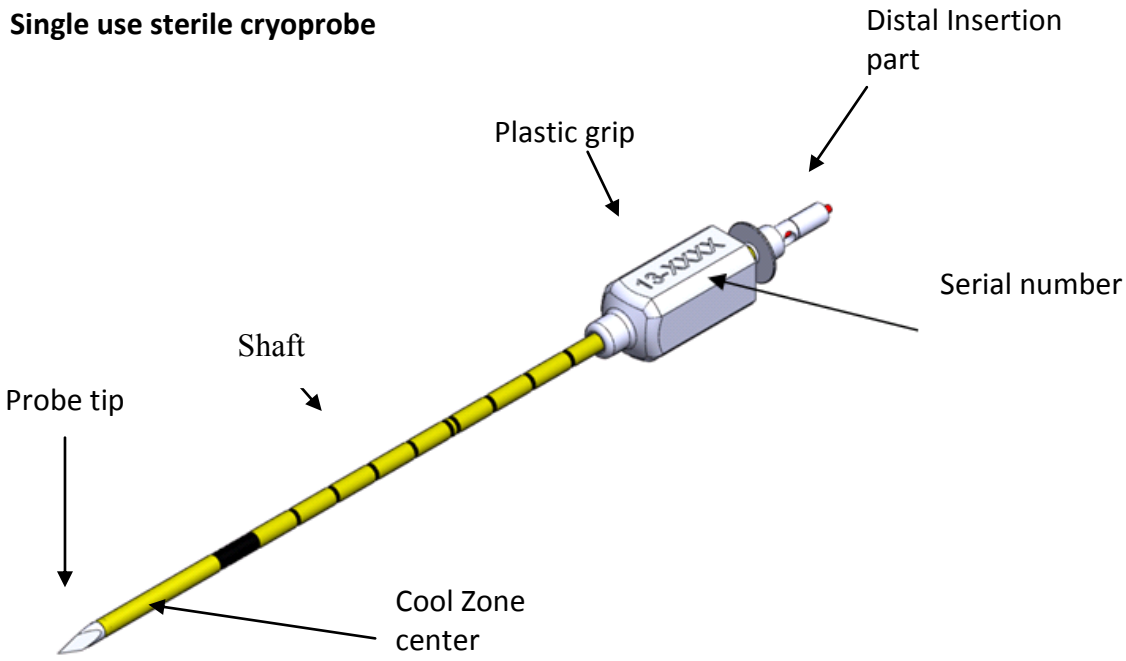


Figure 83: The cryoprobe components (the figure is for illustration only).

There are various cryoprobe configurations. For example:

Probe name	Length (shaft + tip, ± 3 mm)	Diameter	Tip	Iceball shape	Cool zone center (distance from the tip)
FAP7100000 (3.4 Short)	127 mm	3.4 mm	Trocar	Spheric	12 mm
FAP7200000 (3.4 Long)	140 mm	3.4 mm	Trocar	Elliptic	20 mm
FAP7300000	172 mm	3.4 mm	Pencil	Spheric	12 mm
FAP7400000	185 mm	3.4 mm	Pencil	Elliptic	20 mm
FAP7410000	185 mm	3.4 mm	Trocar	Elliptic	20 mm
FAP7500000	392 mm	3.4 mm	Pencil	Spheric	12 mm
FAP7700000	403 mm	3.4 mm	Pencil	Elliptic	19 mm
FAP7600000 (2.4 Short)	125 mm	2.4 mm	Trocar	Spheric	10 mm

FAP7800000 (2.4 Long)	133 mm	2.4 mm	Trocar	Elliptic	14 mm

The IceSense3 cryoprobes are available in various diameters (2mm to 3.4mm), various iceball shapes (Spheric, Ellipsoid), various tips (trocar, blunt and pencil) and various lengths (126mm to 421mm external shaft length) according to the expected application, treated tumor size and surgery approach.

Certain configurations are not available in some regions.

Insert the cryoprobe based on iceball size you want to obtain and the cooling zone location as defined in the table above.

Always monitor the ice ball engulfment with appropriate imaging modality.

Marks on cryoprobe shaft aid in determining the depth of probe insertion. The first mark (closest to the tip) is thicker and represents the minimum insertion depth of the cryoprobe for a percutaneous procedure. Before starting the freezing procedure, the user must verify that this mark is fully inserted into the skin.

7.2 The foot pedal (Not available in some regions, e.g. China)

The foot pedal (Not available in some regions, e.g. China) is a pneumatic accessory, external to the main chassis and is not essential for normal functioning of the system. It serves as an alternative to the Action button on the cryohandle.

To use the foot pedal (Not available in some regions, e.g. China), connect it to the console by plugging its cable into the footswitch connector located on the back panel. The foot pedal action is equal to the action of the BLUE button.

7.3 The temperature sensor (Not available in some regions, e.g. China)

The temperature sensor is a single-use external accessory that can be connected to the main chassis if the user chooses to measure target tissue temperature during cryoablation.
To use the temperature sensor, connect it to the panel connector on the right upper corner of the chassis according to instructions detailed in section 3.3.7 – Temperature sensor.

8 SYSTEM MAINTENANCE

8.1 General cleaning

Warning
Do not allow any liquid or humidity to enter the cryohandle. Always keep the cover on the cryohandle.

Following each cryosurgical procedure, discard the single use devices (single-use cryoprobe, single-use temperature sensor, cryohandle cover, and sleeves for the flexible hose and touch screen) and carefully clean the flexible hose and the cryohandle with a damp cloth.

All single use devices are considered to be medical waste and must be disposed of in accordance with medical waste laws and hospital standards. Sharp objects such as the cryoprobe and temperature sensor must be disposed of in an adapted container.

Following a cryosurgical procedure, it is recommended to wipe the pedal with a damp cloth and warm soapy water to remove visible soil. Dry it with a clean cloth or with forced air and wrap it in another clean cloth until disinfecting it.
Check the main unit for any remaining blood or tissue. In case these remnants are detected, wipe the infected area with gauze Pads soaked with 70% alcohol. Verify that no visible remnants remain. Wipe the initially cleaned area with approved Medical professional surface disinfecting wipes and dry it in air.

Thoroughly clean the IceSense3™ cryoablation system unit with a damp cloth and warm soapy water. Dry it with a clean cloth. Clean the monitor screen with a soft cloth and a mild window cleaning solution. Take special care to avoid spilling liquid onto the system.

At the end of the day, carefully dry all items and store the system in an appropriate place.

8.2 Sterility

Warning
The cryoprobes and the temperature sensors are single use and are supplied in single use packaging. Never reuse a single-use cryoprobe, temperature sensor, or sterile sleeve. Reprocessing single use device (like the cryoprobe, temperature sensor) could affect the mechanical or performance or microbiological properties of the product.

The sterile sleeves and covers are single-use and are not supplied by IceCure Medical in single use packaging.

The sleeves are used to cover the flexible hose up to the cryoprobe and to cover the touch screen; the cover is used for the cryohandle holder.

8.3 Periodic servicing

Caution

The IceSense3™ cryoablation system is not user-serviceable. Refer all service issues to IceCure Medical's Customer Service Department.

If there is any malfunctioning of the IceSense3™ cryoablation system, please contact IceCure Medical technical support.

The technician should disconnect the system from the electrical outlet before removing external covers of the system.

Periodic servicing will ONLY be performed by IceCure Medical authorized service representatives in compliance to the company service procedures and according to the procedure counter that can be seen in the bottom of the main menu screen (see figure below).

Figure 84: Counter of the remaining procedure before maintenance (green arrow) at the bottom of the main menu screen.

Caution

The system will not allow additional treatment when zero procedures left to maintenance. Make sure to call IceCure Medical service representatives in time.

9 TROUBLESHOOTING

9.1 General

Warning
Do not modify this equipment without authorization of the manufacturer

Warning
Never open the console. Only an IceCure Medical technician or authorized representative is allowed to open the console for maintenance or to repair the system.

Warning
Do not attempt to perform any troubleshooting or corrective action beyond those specified in the following guide. Any malfunction not listed in the guide, or one that persists after the recommended action has been taken, **must be referred to IceCure Medical.**

9.2 Troubleshooting guide

Problem	Probable Cause	Action
Main chassis does not move	Wheels are locked	Unlock the wheels, transport the system and lock them again. If the problem persists, contact IceCure Medical service.
No system power	AC power is not connected to the system; power supply malfunction	Check that the power cable is connected to the inlet and the wall outlet. Check that Emergency button is released. Check that main switch is ON. If still there is no power, contact IceCure Medical service.
AC power is on but the screen does not turn on	Computer power supply malfunction or computer error	Check if the computer power cable is connected to the screen and turn the screen on. If the screen still does not turn on, contact IceCure Medical service.
Dewar compartment door does not open	Door held shut by magnet	Try to open the door using reasonable force.

Problem	Probable Cause	Action
		If door will not open, contact IceCure Medical service.
The door is open but the Dewar is not visible	Carriage is not in correct position.	Turn the system off and try to restart the system. If the Dewar is still in its upper position contact IceCure Medical service.
Dewar is jammed and cannot be removed.	Dewar is not in place or is blocked by an unknown object.	If Dewar cannot be removed, close the door, and contact IceCure Medical service.
System provides "Wrong cryoprobe S/N" message.	System identifies wrong or double use of the cryoprobe.	Verify that the number you entered matches the one on the cryoprobe and the package. If S/N is correct, reenter it into the system. If the message reappears, change the cryoprobe and call IceCure Medical service.
"Connect the probe" message displayed constantly on the screen	Faulty microswitch	Ensure that the probe is fully inserted (can't screw it any more with reasonable force). If "next" button doesn't appears, change cryoprobe. If the problem persists, contact IceCure Medical service.
Freeze/Warm icon does not initiate the operation	Faulty icon or operator misuse.	Try pushing the icon again. It is only activated if pushed for 1 second. Check the user manual to ensure that you can indeed use the icon in the present screen. If the problem persists contact IceCure Medical service.
LED does not light up	Burned out LED, or it should not be lighting up at given time.	Check user manual to verity that the LED should light up. If yes, contact IceCure Medical service.
Ice formation on the flexible hose, the cryohandle and sterile sleeve	Low temperature and long freezing cycles may causes moisture to form ice particles.	This is not an operational problem. Wipe off accumulated ice with clean sterile gauze.
Nitrogen leaks from cryoprobe, cryohandle or system during the cryotherapy procedure.	Cryoprobe is not well connected or pipes are faulty.	Push the Warm button and contact IceCure Medical service.
Unreasonable temperature readings of temperature sensor	Temperature sensor or system malfunctions.	Check that the temperature sensor is well connected. If so, change the temperature sensor.

Problem	Probable Cause	Action
		If temperature reading is still unreasonable, continue the procedure without a temperature sensor. If problem persists, contact IceCure Medical service.
Cryoprobe cannot easily be removed from target tissue.	Warm process malfunction	Do not use force in attempting to remove the cryoprobe from the tissue. Wait a few minutes and try removing it gently again. If problem persists, contact IceCure Medical service.
Cryoprobe is difficult to detach from cryohandle.	Parts are frozen together	Try again after five minutes. If it still cannot be detached, contact IceCure Medical service.
Nitrogen leak when trying to remove the cryoprobe	Excess pressure on the pipes, main valve open, procedure not completed, or Dewar relief valve malfunction.	When initial leak is detected, screw the cryoprobe back in place. Make sure that the procedure has ended, wait 3 minutes and try removing the cryoprobe again. If nitrogen is still leaking contact IceCure Medical service.
Computer failure due to hardware fault	Unknown	Mechanical shut down of the system using the On/Off switch at the back of the system or emergency stop. Then turn on the system (after releasing the emergency stop button, if pressed) and wait for computer re-boot.
Screen is stuck/ Controller stops working/ Controller is stuck	Unknown	Mechanical shut down of the system using the On/Off switch at the back of the system or emergency stop. Then turn on the system (after releasing the emergency stop button, if pressed) and wait for computer re-boot.

Table 1: Troubleshooting guide

10 IceSense3™ cryoablation system - Step-by-Step procedure

Before starting the procedure a Pre-Test **must be** carried out!

System preparation and Pre-Test

1. Press Prepare for treatment.
2. Remove the Dewar's cap and fill the Dewar with liquid nitrogen **in a safe manner.**
3. Place the Dewar inside the system and close the door.
4. Press Next (by pressing the BLUE button on cryohandle OR by pressing on the console touch screen)
5. Enter the probe serial number. **Each procedure must be carried out with a new sterile probe. Press on the 'Next' button on the screen.**
6. Remove the handle's cap, attach the probe to the handle and press Next. The 'Next' button will be shown only when the probe is connected properly.
   The following message will appear - **"Please wait until the system is ready for test"**
7. When the system is ready, place the probe inside a sterile Saline or water cup.
8. Press Test (by pressing the BLUE button on cryohandle OR by pressing on the console touch screen). **Notice that you don't see any bubbles, that the shaft is not frozen,and that a small ice-ball is created at the tip of the probe.**
9. If the test was successful press Success. If not, start over with a new sterile probe if required.

Procedure

10. Select treatment modality: Preset Cycles/ Manual Mode. You can modify the cycles as needed **during procedure.**
11. Insert the probe to the tissue and navigate with the help of Ultrasound to stub through the lesion center.
12. Activate treatment cycle: Press FREEZE on the console touch screen, OR Press the BLUE button on cryohandle.
    - Monitor ice-ball under ultrasound at all times.
    - Inject saline buffer as needed to protect the skin.
    - You may manually stop the first freeze cycle and start the Thaw process by pressing Skip. This is done by pressing the BLUE button on cryohandle OR by pressing on the console touch screen.
    - You may manually stop the second freeze cycle and start the Warm process by pressing Warm. This is done by pressing the BLUE button on cryohandle OR by pressing on the console touch screen.
13. During the warm process gently remove the probe. When the warm process is finished you can press finish if you have manage to remove the probe from the body or continue the warm process by pressing Warm and try again to gently remove the probe.
    - **If you press Warm more than two times, the following message may appear -**

      "Please wait for passive Thaw"

      In this case wait for passive thaw and gently extract the probe from the tissue**.**
14. Do not disengage the probe from the handle until the following message appears -

    "Safe to disengage the probe from the handle"
15. After disengaging the probe, immediately replace the handle's cap.

Warning messages - Critical information will appear as a pop-up dialog with an "OK" button for acknowledging the message.
Error messages- Information that prevents the user from continuing the operation of the system will appear as a dialog box that cannot be closed, stating the problem and possible solutions. **When such a message appears, the user should carefully follow system instructions.**

11 SYSTEM SPECIFICATIONS

Physical properties	Dimensions (excluding the screen)	Height: 120 cm (47.24 inches) Depth: 70 cm (27.56 inches) Width: 50 cm (19.68 inches)
	Weight	150kg
Electrical requirements		220-240 VAC 7 A 50/60 Hz, single phase
Operating pressure	Pressure range	0-100 psi
Cryogen	Liquid Nitrogen	Boiling point: -196° C
Type of cryometer		thermocouple type K
Environmental conditions	Temperatures:	
	Operating	10° C; +40° C (50° F; 104° F)
	Transportation and Storage	0° C; +70° C (32° F ; 158° F)
	Relative Humidity:	
	Operating	0 up to 80% not condensing at room temperature
	Transportation and Storage	0 up to 90% not condensing
	Atmospheric pressure:	
	Operating	700 hPa; 1060 hPa
	Transportation and Storage	500 hPa; 1060 hPa
Temperature range of cryoprobe:		-196° C to +40° C
Temperature range of Temperature sensor:		-196 °C to +260 °C
Pressure sensor		Power supply 24 V Pressure range: 0.1 - 145 psi Accuracy 1% Repeatability ≤ ± 0.1

12 LIMITED WARRANTY CERTIFICATE

Terms and conditions for warranty of purchased medical equipment.

Warranty Number: _____

Date of Issue: _____

We, as sellers of the equipment, warrant that for a period ending twelve (12) months from the date of supply of the equipment as stated below, the equipment shall be free from defects in material and workmanship.

Our sole liability under valid warranty claims shall be limited, at our option, to repair or replace defective parts. All warranty replacement or repair of parts shall be limited to equipment malfunction which, in our reasonable opinion, are due and traceable to defects in original material and workmanship.

In order to enable us to properly administer this warranty, buyer shall notify us promptly in writing of any claims and shall provide us with the opportunity to inspect and test each item claimed to be defective. Such inspection may be at our laboratory. Replacement or repair shall be contingent upon our examination, disclosing that defects have not been caused by misuse, abuse, improper application, improper electrical supply (as specified in the equipment's official user manual), unauthorized transfer of ownership, unauthorized repair, alternation, accident or negligence. Geographic relocation of the equipment may, at our reasonably exercised option, result in exclusion of the equipment from warranty coverage. This warranty shall not apply to electron tubes, lamps, fuses, batteries and any other parts which carry separate warranties based upon usage.

The warranties contained herein are in lieu of all other warranties, express or implied, as to the condition, merchantability, fitness for a particular purpose, or any other matter concerning the equipment or its use or performance. Buyer hereby waives any claim it may have against seller for any loss, damage, or expense of any kind whatsoever, caused by any defect therein, the use or maintenance thereof, or any servicing or adjustments thereto, not expressly covered by the warranties contained herein.

Buyer further agrees that seller will not be liable for any incidental, consequential or special damages, for any lost profits, or for any claim or demand against the buyer by any other party.

Seller's liability for damages under this warranty shall in no event exceed the purchase price.

Seller shall not be required to perform seller's obligations under this agreement, or be liable for seller's failure to perform, if non-performance is caused by an Act of God, war, civil disturbance, strike, work stoppage, transportation contingencies, power failures, laws, regulations, ordinances, acts or orders of any governmental agency of official thereof, or any cause not within the control of the seller.

Warranty Number:_____

Date of supply of equipment:_____

Date of expiration of this warranty certificate:_____

Buyer of the equipment:_____

IceCure Medical representative:_____

13 CUSTOMER COMPLAINT FORM

Section 1: Customer complaint
(To be filled by customer / complaint recipient)

Initial Disposition: ☐ **Customer Complaint**
☐ **Service Call/Activity#**_____
(in case of two dispositions please fill SC form FQM-75-005-0 – The No. will be filled by QA).

Reported by: ☐ **Phone** ☐ **FAX** ☐ **Email** ☐ **Letter** ☐ **Sales representatives** ☐ **Website**
☐ **Distributer Company** _____ ☐ **Other:** _____

Name: _____ **Title / Position:** _____

Address: _____

Phone: _____ **Fax:** _____

Product Name: (Please include all machine#, probes# and TS# used)	**Batch No. :**	**Serial No. :**

SW Ver. _____
Is a sample available? ☐ **Yes** ☐ **NO** ☐ **Picture** ☐ **Other:**_____
(Please assign RMA# and Tag to the sample sent)
Is sample disinfected according to WI-1036 (Utilization of Probe after Field Return (clinically used))
☐ **Yes** ☐ **NO** ☐ **NA**

Complaint occurred during: ☐ **Installation** ☐ **pretest** ☐ **procedure** ☐ **follow up**
☐ **Other:** _____

Description of complaint: (Please include SW# used in the case)

_____

_____

Was clinical procedure completed? ☐ **Yes** ☐ **NO** ☐ **NA:**_____
Please describe the clinical procedure:

_____

_____

_____

Type of malfunction: ☐ **System** ☐ **Software** ☐ **Probe** ☐ **Dewar** ☐ **Transportation**
☐ **Other:** _____

Initial consequences: ☐ **No Harm** ☐ **Injury** ☐ **Death**
If death or injury occurred, please describe below

_____

Complaint recorded by:

Name: _____ **Title / Position:** _____
On Date: Click here to enter a date. **Time:** _____
Signature: _____

ATTENTION! IF DEATH OR INJURY OCCURRED NOTIFY IMMEDIATELY TO ALL RELEVANT PERSONNEL ACCORDING TO PROCEDURES

14 REPORT CUSTOMER COMPLAINT

Send to:

IceCure Medical, Inc.
498 Halle Park Dr., Ste. 102
Collierville, TN 38017
icecuresupport@icecure-medical.com
Toll-free 888-516-7389
Tel 901.316.5672
Fax 901.316.5944

OR:

IceCure Medical Ltd.
HaEshel 7, 2nd floor
Southern Industrial Park,
Caesarea 38900, Israel
info@icecure-medical.com
Tel: +972-4-623 0333;
Fax: +972-4-623 0222

EC REP

MedNet GmbH – Authorized Representative of IceCure Medical Ltd.
Borkstraße 10
48163 Münster
Germany
Tel +49 (0) 251 32266-0
Fax +49 (0) 251 32266-22

16 Manufacturer's Declaration of the EUT

Guidance and manufacturer's declaration-electromagnetic emission- for all EQUIPMENT AND SYSTEMS

1	Guidance and manufacturer's declaration-electromagnetic emission		
2	The model IceSense3 Cryotherapy product is intended for use in the electromagnetic environment specified below. The customer or the user of the model IceSense3 Cryotherapy product should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 1	The model IceSense3 Cryotherapy product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class B	
6	Harmonic emissions EN 61000-3-2	Class A	
7	Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

Guidance and manufacturer's declaration-electromagnetic immunity- for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration-electromagnetic immunity</th></tr>
<tr><td colspan="4">The model IceSense3 Cryotherapy product is intended for use in the electromagnetic environment specified below. The customer or the user of the model IceSense3 Cryotherapy product should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment- guidance</th></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile RF communications equipment should be used no closer to any part of the model IceSense3 Cryotherapy product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td></tr>
<tr><td>Conducted RF EN 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 V</td><td>Recommended separation distance
$d = [\frac{3,5}{V_1}]\sqrt{P}$
$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz</td></tr>
<tr><td>Radiated RF EN 61000-4-3</td><td>3 V/m
80 MHz to 2,5 GHz</td><td>3 V/m</td><td>$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz
where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b
Interference may occur in the vicinity of equipment marked with the following symbol:</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model IceSense3 Cryotherapy product is used exceeds the applicable RF compliance level above, The model IceSense3 Cryotherapy product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model IceSense3 Cryotherapy product.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM- for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the model IceSense3 Cryotherapy product			
The model IceSense3 Cryotherapy product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model IceSense3 Cryotherapy product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model IceSense3 Cryotherapy product as recommended below, according to the maximum output power of the communications equipment.			
	Separation distance according to frequency of transmitter m		
Rated maximum output of transmitter W	$d = [\frac{3,5}{V_1}]\sqrt{P}$)MHz	$d = [\frac{3,5}{E_1}]\sqrt{P}$) MHz	$d = [\frac{7}{E_1}]\sqrt{P}$,5 GHz
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			